# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

# AMENDMENT NO. 2 TO FORM S-1 REGISTRATION STATEMENT

UNDER
THE SECURITIES ACT OF 1933

# MeiraGTx Holdings plc

(Exact name of registrant as specified in its charter)

Cayman Islands

(State or other jurisdiction of incorporation or organization)

2836

(Primary Standard Industrial Classification Code Number)

Not applicable

(I.R.S. Employer Identification No.)

430 East 29th Street, 10th Floor New York, NY 10016 (646) 490-2965

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Alexandria Forbes, Ph.D. MeiraGTx LLC 430 East 29th Street, 10th Floor New York, NY 10016 (646) 490-2965

(Name, address, including zip code, and telephone number, including area code, of agent for service)

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# Approximate date of commencement of proposed sale to the public: As soon as practicable after this Registration Statement is declared effective.

Securities Act of 1933, check the following box. $\Box$	to be offered off a delayed of Colli	nuous basis pursuant to R	ule 415 under the
If this Form is filed to register additional securities for an	a offering purcuant to Pulo 462(b)	under the Securities Act	shook the following boy
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Indicate by check mark whether the registrant is a large a company or an emerging growth company. See the definitions of "la" "emerging growth company" in Rule 12b-2 of the Exchange Act.			
Large accelerated filer		Accelerated filer	
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The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Subject to Completion
Preliminary Prospectus dated May 29, 2018.

# **PROSPECTUS**



# **Ordinary Shares**

This is MeiraGTx Holdings plc's initial public offering. We are offering 5,000,000 of our ordinary shares.

We expect the initial public offering price to be between \$14.00 and \$16.00 per ordinary share. Currently, no public market exists for our ordinary shares. After pricing of the offering, we expect that our ordinary shares will trade on the Nasdaq Global Select Market under the symbol "MGTX."

We are an "emerging growth company" under the federal securities laws and are subject to reduced public company disclosure standards. See "Prospectus Summary—Implications of Being an Emerging Growth Company."

Investing in our ordinary shares involves risks that are described in the "<u>Risk Factors</u>" section beginning on page 13 of this prospectus.

	Per Share	Total
Public offering price	\$	\$
Underwriting discount(1)	\$	\$
Proceeds, before expenses, to us	\$	\$

<sup>(1)</sup> We refer you to "Underwriting" beginning on page 207 for additional information regarding underwriting compensation.

The underwriters may also exercise their option to purchase up to an additional 750,000 ordinary shares from us, at the public offering price, less the underwriting discount, for 30 days after the date of this prospectus.

Certain of our existing shareholders and their affiliated entities have indicated an interest in purchasing an aggregate of up to approximately \$40.0 million of our ordinary shares in this offering at the initial public offering price per share and on the same terms as the other purchasers in this offering. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could determine to sell more, fewer or no shares to any of these potential purchasers, and any of these potential purchasers could determine to purchase more, fewer or no shares in this offering. The underwriters will receive the same underwriting discount and commissions on these shares as they will on any other shares sold to the public in this offering.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The ordinary shares will be ready for delivery on or about , 2018.

Joint Book-Running Managers

**BofA Merrill Lynch** 

**Barclays** 

**Evercore ISI** 

Lead Manager

Chardan

The date of this prospectus is

, 2018.

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Neither we nor the underwriters have authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectus prepared by or on behalf of us or to which we have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the shares offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus or in any applicable free writing prospectus is current only as of its date, regardless of its time of delivery or any sale of our ordinary shares. Our business, financial condition, results of operations and prospects may have changed since that date.

For investors outside the United States: Neither we nor the underwriters have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the ordinary shares and the distribution of this prospectus outside the United States.

#### ABOUT THIS PROSPECTUS

Prior to the completion of this offering, we will undertake a corporate reorganization, pursuant to which MeiraGTx Limited will become a wholly owned subsidiary of MeiraGTx Holdings plc, an exempted company incorporated under the laws of the Cayman Islands with nominal assets and liabilities, which will not have conducted any operations prior to this offering other than acquiring the entire issued share capital of MeiraGTx Limited and other actions incidental to such acquisition and its incorporation. MeiraGTx Holdings plc will be the issuer of ordinary shares in this offering. Following the corporate reorganization, our financial statements will present the results of operations of MeiraGTx Holdings plc and its consolidated subsidiaries.

Unless otherwise indicated or the context otherwise requires, all references in this prospectus to the terms "MeiraGTx," the "Company," "we," "us" and "our" refer to MeiraGTx Limited and its wholly owned subsidiaries prior to the completion of our corporate reorganization and MeiraGTx Holdings plc and its subsidiaries after the completion of our corporate reorganization.

We have proprietary rights to trademarks, trade names and service marks appearing in this prospectus that are important to our business. Solely for convenience, the trademarks, trade names and service marks may appear in this prospectus without the ® and TM symbols, but any such references are not intended to indicate, in any way, that we forgo or will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensors to these trademarks, trade names and service marks. All trademarks, trade names and service marks appearing in this prospectus are the property of their respective owners.

#### PROSPECTUS SUMMARY

This summary highlights, and is qualified in its entirety by, the more detailed information and financial statements included elsewhere in this prospectus. This summary does not contain all of the information that may be important to you in making your investment decision. You should read this entire prospectus carefully, especially the "Risk Factors" section beginning on page 12 and our consolidated financial statements and the related notes appearing at the end of this prospectus, before deciding to invest in our ordinary shares.

#### Overview

We are a vertically integrated, clinical stage gene therapy company with four ongoing clinical programs and a broad pipeline of preclinical and research programs. We have core capabilities in viral vector design and optimization and gene therapy manufacturing, as well as a potentially transformative gene regulation technology. Led by an experienced management team, we have taken a portfolio approach by licensing, acquiring and developing technologies that give us depth across both product candidates and indications. Though initially focusing on the eye, salivary gland and central nervous system, we intend to expand our focus in the future to develop additional gene therapy treatments for patients suffering from a range of serious diseases.

We operate a flexible and scalable viral vector manufacturing facility that we expect can supply our current clinical and preclinical programs through regulatory approval and, should they be approved, provide sufficient capacity for commercial production. Completed in early 2018 and designed to meet global regulatory requirements, including the current good manufacturing practices, or cGMP, required by the U.S. Food and Drug Administration, or FDA, our 29,000 square foot facility has two cell production suites, three independent viral vector production suites providing multi-product and multi-viral vector manufacturing capabilities and an integrated, flexible fill-and-finish suite. In May 2018, we were granted a license to manufacture gene therapy product candidates in our cGMP compliant manufacturing facility by the UK Medicines and Healthcare products Regulatory Agency.

We have also established a comprehensive platform for the efficient clinical development of the next generation of gene therapies and manufacturing in accordance with cGMP. Our deep understanding of disease models informs our development of potency assays for the cGMP production of our product candidates, and our teams experienced in viral vector design work closely with our process development team to design viral vectors and develop proprietary production cell lines for efficient scaling of manufacturing processes.

We are also developing a potentially transformative technology to enable the use of small molecules to turn gene therapy product candidates on and off. The aim of this gene regulation platform is to convert gene therapy into a generalizable delivery mechanism for biologic drugs using a small molecule "switch" for temporal control. We believe the capacity for temporal control of gene therapy products has the potential to transform the gene therapy landscape by opening up new treatment possibilities.

# **Our Pipeline**

Our initial focus is on three distinct areas of unmet medical need: inherited retinal diseases, or IRDs, severe forms of xerostomia and neurodegenerative diseases. Utilizing our product development platform, we have assembled a pipeline of gene therapies to treat these serious diseases. Our criteria for selecting our initial product candidates included:

- unmet medical need;
- high potential for meaningful clinical benefit;
- promising preclinical data using multiple animal models as well as human stem cell derived organoids;

- compartmentalized anatomy of target tissue and the partially immune protected nature of target tissue; and
- understanding of the disease state from natural history studies and detailed long-term characterization of patients prior to entry into gene therapy treatment studies.

A summary of our product candidates is below. We retain worldwide development and commercialization rights to all of our product candidates.

Product	Indication	Development Stage		Stage	Status		
Candidate	indication	Preclinical	Phase 1/2	Phase 3	Status		
Ophthalmolog	y Programs						
AAV-CNGB3	Achromatopsia (CNGB3)	Orphan U.S. & EU RPDD; PRIME 12.23	i.		Phase 1/2 ongoing in UK <sup>(5)</sup>		
AAV-CNGA3	Achromatopsia (CNGA3)				Phase 1/2 expected initiation in 2019		
AAV-RPGR	X-linked RP (RPGR)	Orphan U.S. & EU Track Designation/	; Fast		Phase 1/2 ongoing		
AAV-RPE65	RPE65-Deficiency (RPE65)	Orphan U.S. & EU RPDD <sup>(1,2,3)</sup>			Phase 1/2 ongoing		
A006	Wet AMD (anti-VEGFR2)				First in man clinical trials expected 2019		
Salivary Glan	d Programs						
AAV-AQP1	Xerostomia (hAQPI)	Orphan U.S.			Phase 1 ongoing		
AAV-AQP1	Sjogren's (hAQPI)				Phase 1/2 expected initiation in 2019		
Neurodegener	ative Diseases Prog	ram					
AAV-UPF1	ALS (UPF1)				First in man clinical trials expected 2019		

Orphan drug designation by the FDA.
Orphan drug designation by European Medicines Agency, or the EMA.
Rare pediatric disease designation by Offices of Orphan Products Development and Pediatric Therapeutics of the FDA.
Priority medicines, or PRIME, designation by the EMA.
The IND for AAV-CNGB3 has not been opened yet because the FDA had a question about our device compatibility assay, placing the IND on clinical hold until the question has been exiferentially appropried. 1. 2. 3. 4. 5. been satisfactorily answered. Fast Track designation by the FDA.

In addition to these clinical and preclinical programs, we have preclinical and research programs in other indications and novel molecular technologies that we aim to advance into clinical development, including:

- neovascular age related macular degeneration, or wet AMD use of a gene therapy product to deliver an antibody targeting the vascular endothelial growth factor receptor 2, or anti-VEGFR2, with the aim of blocking disease related vascular formation in the eye;
- geographic atrophy age related macular degeneration, or dry AMD use of gene therapy technology to introduce light sensitive molecules into rod photoreceptors in order to restore some aspects of vision lost in this disease;
- amyotrophic lateral sclerosis, or ALS targeting dysregulation of neuronal RNA processing, which we believe may lead to the degeneration of motor neurons that occurs in ALS;
- Alzheimer's disease targeting endosomal trafficking, which is a central mechanism that we believe underlies Alzheimer's disease; and
- gene regulation use of our proprietary RNA shape regulation cassette to switch gene therapy product candidates on and off with small molecules, potentially transforming gene therapy technology into a delivery mechanism for a broad array of biologic drugs.

#### **Our Ophthalmology Programs**

Eye diseases are our first area of clinical focus and we aim to provide treatments with durable, long-term clinical benefit that will halt vision loss in patients. We currently have three ongoing clinical programs in IRDs with an additional program expected to initiate a Phase 1/2 clinical trial in 2019. The targets of our three ongoing Phase 1/2 ophthalmology programs include achromatopsia related to mutations in *CNGB3*, X-linked retinitis pigmentosa related to mutations in *RPGR*, and inherited retinal dystrophy caused by mutations in *RPE65*. We also have a product candidate that was manufactured and released for compassionate use under a specials license in the United Kingdom to treat patients with Leber congenital amaurosis 4, or LCA4, caused by mutations in *AIPL1*. For each of our Phase 1/2 clinical programs, we also have a prospectively designed natural history study ongoing, which includes the same endpoints as our corresponding gene therapy treatment trial. We believe use of these natural history studies differentiates our programs by providing patient populations to facilitate the efficient execution of our clinical trials and offering insight into the appropriate endpoints for regulatory approval of our gene therapy product candidates. In addition to these clinical programs, we have preclinical programs that apply novel approaches to both wet and dry AMD.

The FDA and EMA have granted orphan drug designation to each product candidate in our ongoing clinical programs, including those treating mutations in *CNGB3*, *RPGR* and *RPE65*, as well as our product candidate to treat mutations in *AIPL1*. The FDA also granted rare pediatric disease designation for our clinical programs treating mutations in *RPE65* and *CNGB3* and Fast Track designation to our clinical program treating XLRP caused by mutations in *RPGR*. We have also received PRIME designation from the EMA for our clinical program treating mutations in *CNGB3*.

The deep scientific and clinical understanding of IRDs driving our approach to gene therapy development helps us to optimize our product candidates for each specific genetic mutation and phenotype. We develop our viral vectors by selecting and modifying proprietary cell specific promoters, selecting appropriate capsids for transfection of target cells and refining the vector for efficient production and scalable manufacturing. Not only does this allow us to synergistically target a portfolio of inherited eye conditions, we also believe it has potential to be applied to the development of gene-based therapies for other diseases.

Our longstanding relationships with leading institutions in retinal disease treatment, including Moorfields Eye Hospital in London, the University of Michigan Kellogg Eye Center, Massachusetts Eye and Ear,

the Medical College of Wisconsin & Froedtert Hospital and the Casey Eye Institute at the Oregon Health & Science University, provide us with access to experts whose guidance and insight informs our development strategy, as well potential patients for our clinical trials.

# **Our Salivary Gland Programs**

Our second area of clinical focus is xerostomia, a chronic and debilitating disorder of the salivary glands in which saliva production is impaired. Xerostomia may be caused by a number of different insults to the salivary glands, including radiation therapy for head and neck cancer and certain autoimmune diseases. A Phase 1 clinical trial of our gene therapy product candidate, AAV-AQP1, is ongoing in patients who have survived cancer free for five or more years following treatment for head and neck cancer and are suffering from grade 2 or 3 radiation induced late xerostomia, or RIX. There are approximately 170,000 grade 2 or 3 RIX patients who have survived two or more years after radiation treatment for head and neck cancer in the United States, with approximately 10,000 new cases each year. We also intend to initiate a Phase 1/2 clinical trial of AAV-AQP1 for the treatment of patients with chronic xerostomia caused by Sjogren's syndrome, an autoimmune disease affecting more than two million people in the United States.

The FDA has granted orphan drug designation to AAV-AQP1.

# **Our Neurodegenerative Disease Programs**

Neurodegenerative diseases are our third area of focus. Our first target indication is ALS and we expect to file an investigational new drug application, or IND, and initiate a clinical trial of our first product candidate for the treatment of ALS in 2019. We believe our approach to treating ALS patients is differentiated because, rather than targeting a specific genetic defect that defines a small subset of ALS patients, we aim to target the underlying cell biology driving motor neuron death in ALS, potentially enabling us to treat a broader patient population that includes both sporadic and inherited forms of the disease. Increasing evidence suggests a critical role of RNA metabolism in neuronal cells, in particular in motor neurons that are specifically affected in ALS. We believe that dysregulation of neuronal RNA processes results in the degeneration of motor neuron that leads to ALS. Using our viral vector product candidate, AAV-UPF1, we target the central quality control system regulating RNA in motor neurons with the aim of enhancing motor neuron survival in ALS patients.

We have an Alzheimer's disease program that is likewise directed towards the underlying cell biology of the disease, in this case endosomal trafficking, a mechanism cells use to cycle proteins to the cell surface. Over the past decade, evidence has emerged supporting endosomal trafficking dysfunction in neurons as a central process in the early etiology of Alzheimer's disease. In particular, a master regulator of trafficking out of the endosomes called retromer has been implicated. We are in the process of identifying the optimal approach to restoring normal endosomal function to the neurons that are the first to be affected in Alzheimer's disease and appear to drive the initiation of the disease. In parallel, we are developing and validating biomarkers of endosomal dysfunction and pre-symptomatic Alzheimer's disease. We believe this approach may also provide a framework for treating certain forms of Parkinson's disease that are also associated with endosomal dysfunction.

# **Our Strengths**

In addition to our four ongoing clinical programs, we have a broad pipeline of preclinical programs, core capabilities in viral vector design and optimization, gene therapy manufacturing and a potentially transformative gene regulation technology. Utilizing the following key strengths, we aim to develop, commercialize and expand our portfolio of gene therapy product candidates.

• **Deep Expertise in Gene Therapy Development:** Our expertise in viral vector design, optimization and process development allows us to efficiently advance gene therapy product candidates from preclinical development to cGMP manufacturing and human clinical development through commercialization.

- Potentially Transformative Gene Regulation Technology Platform: We are developing proprietary technology for innovative
  gene therapy treatments whose expression can be turned on and off with an easily administered small molecule. We believe the
  capacity for temporal control of gene therapy products has the potential to transform the gene therapy landscape by opening up new
  treatment possibilities.
- **Manufacturing Capabilities and Capacity:** We have a flexible and scalable cGMP manufacturing facility and production process, which we expect can supply all of our current clinical and preclinical programs through regulatory approval and, should they be approved, provide sufficient capacity for their commercial production.
- **Robust and Diverse Clinical and Preclinical Pipeline:** Applying our portfolio approach to gene therapy product development, our initial focus is on treatments for IRDs, salivary glands disorders and neurodegenerative diseases with potential for accelerated approval and has produced four ongoing clinical programs and multiple preclinical development programs.
- **Relationships with Leading Institutions:** Our longstanding relationships with leading institutions and experts provides us with guidance on development strategy and access to potential patients for our clinical trials.
- Natural History Study Data: We sponsor ongoing prospective long-term natural history studies in IRDs that facilitate our ability
  to efficiently enroll our treatment studies, potentially reducing clinical trial timelines and providing insight into the appropriate
  endpoints for regulatory approval.

#### **Our Strategy**

Our goal is to develop and commercialize innovative gene therapy products to treat serious disorders and broaden the scope of indications that may be treatable by our gene therapies. Our strategy to achieve this goal is to:

- successfully complete clinical development, obtain regulatory approval and commercialize our pipeline of gene therapy product candidates to treat disorders of the eye and salivary gland;
- continue to advance the development of our pipeline of gene therapy product candidates for the treatment of neurodegenerative disorders;
- · utilize our viral vector design and optimization capabilities to identify and develop new gene therapies for other serious diseases;
- advance the development of our potentially transformative proprietary technology for regulating the activity of gene therapy
  products using small molecules and initiate clinical trials of new product candidates; and
- evaluate strategic collaborations with other biotechnology and pharmaceutical companies to leverage our capabilities, manufacturing capacity and proprietary gene regulation technology.

#### **Risk Factors**

Our business is subject to numerous risks and uncertainties, including those highlighted in the section titled "Risk Factors" immediately following this prospectus summary. Some of these risks are:

• We have incurred significant losses since inception and anticipate that we will incur continued losses for the foreseeable future, and may never achieve or maintain profitability.

- · We will require additional capital to fund our operations, which may not be available on acceptable terms, if at all.
- We are heavily dependent on the success of AAV-CNGB3, AAV-CNGA3, AAV-RPGR, AAV-RPE65 and AAV-AQP1, our most
  advanced product candidates, which are still in development, and if none of them receive regulatory approval or are successfully
  commercialized, our business may be harmed.
- We intend to identify and develop product candidates based on our novel gene therapy platform, which makes it difficult to predict
  the time and cost of product candidate development. Very few products that utilize transduction technology have been approved in
  the United States or in Europe, and there have only been a limited number of human clinical trials involving gene therapy product
  candidates.
- Because gene therapy is novel and the regulatory landscape that governs any product candidates we may develop is uncertain and
  may change, we cannot predict the time and cost of obtaining regulatory approval, if we receive it at all, for any product candidates
  we may develop.
- Clinical trials are expensive, time-consuming, difficult to design and implement, and involve an uncertain outcome. Further, we
  may encounter substantial delays in our clinical trials.
- The affected populations for our other product candidates may be smaller than we or third parties currently project, which may affect the addressable markets for our product candidates.
- We and our contract manufacturer for plasmid are subject to significant regulation with respect to manufacturing our products. Our manufacturing facilities and the third-party manufacturing facility which we rely on may not continue to meet regulatory requirements and have limited capacity.
- We depend on proprietary technology licensed from others. If we lose our existing licenses or are unable to acquire or license additional proprietary rights from third parties, we may not be able to continue developing our product candidates. In addition, if we are unable to obtain and maintain patent protection for our technology and product candidates or if the scope of the patent protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets.
- We face significant competition in an environment of rapid technological change, and there is a possibility that our competitors may achieve regulatory approval before us or develop therapies that are safer or more advanced or effective than ours, which may harm our financial condition and our ability to successfully market or commercialize any product candidates we may develop.

# Implications of Being an Emerging Growth Company

As a company with less than \$1.07 billion in revenue during our last fiscal year, we qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, as amended, or JOBS Act. An "emerging growth company" may take advantage of reduced reporting requirements that are otherwise applicable to public companies. These provisions include, but are not limited to:

- being permitted to present only two years of audited financial statements and only two years of related Management's Discussion and Analysis of Financial Condition and Results of Operations in this prospectus;
- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended;

- reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

We may take advantage of these provisions until the last day of 2023. However, if certain events occur prior to the end of 2023, including if we become a "large accelerated filer," our annual gross revenue exceeds \$1.07 billion or we issue more than \$1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of 2023.

We have elected to take advantage of certain of the reduced disclosure obligations in the registration statement of which this prospectus is a part and may elect to take advantage of other reduced reporting requirements in future filings. As a result, the information that we provide to our shareholders may be different than you might receive from other public reporting companies in which you hold equity interests.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. We have elected to take advantage of this extended transition period.

# **Corporate Information**

MeiraGTx Holdings plc was formed on May 1, 2018 under the laws of the Cayman Islands. The registered office of the Company is situated at the offices of Walkers Corporate Limited, Cayman Corporate Centre, 27 Hospital Road, George Town, Grand Cayman KY1-9008, Cayman Islands. MeiraGTx Limited, a private company formed under the laws of England and Wales, is a subsidiary of MeiraGTx Holdings plc and will be its predecessor accounting entity upon closing of the offering. Our principal executive offices are located at 430 East 29th Street, 10th Floor, New York, New York 10016 and our telephone number is (646) 490-2965. Our website address is <a href="https://www.meiragtx.com">www.meiragtx.com</a>. The information contained in, or accessible through, our website does not constitute a part of this prospectus.

# **Corporate Reorganization**

Following the effectiveness of this registration statement and prior to the start of trading of our ordinary shares on the Nasdaq Global Select Market, we will effect a corporate reorganization, pursuant to which the outstanding shares of MeiraGTx Limited will be exchanged for equivalent shares of MeiraGTx Holdings plc. MeiraGTx Holdings plc will become the direct parent of MeiraGTx Limited and the holding company of the business and will be the issuer of ordinary shares in this offering. We refer to these events in this prospectus as the "Corporate Reorganization." Prior to this offering, MeiraGTx Holdings plc will have only engaged in activities incidental to its formation, the Corporate Reorganization and this offering. Accordingly, financial information for MeiraGTx Holdings plc and a discussion and analysis of its results of operations and financial condition for the period of its operations prior to the Corporate Reorganization would not be meaningful and are not presented. Following the Corporate Reorganization, the historical financial statements of MeiraGTx Limited and its consolidated subsidiaries will present the results of operations of MeiraGTx Holdings plc and its consolidated subsidiaries.

Following the Corporation Reorganization and prior to the start of trading of our ordinary shares on the Nasdaq Global Select Market, we also expect to effect a 1 for 3.881 reverse share split (by way of consolidation of the share capital of the Company) on all outstanding ordinary shares of MeiraGTx Holdings plc and effect a corresponding adjustment to the conversion ratio for our outstanding preferred shares. Prior to the closing of the offering, the preferred shares of MeiraGTx Holdings plc, and the preferred shares issued as a result of the exercise of all outstanding warrants, will convert into A ordinary shares and all A ordinary shares (including those resulting from the conversion of our preferred shares) shall be re-designated as ordinary shares.

# **Indications of Interest**

Certain of our existing shareholders and their affiliated entities have indicated an interest in purchasing an aggregate of up to approximately \$40.0 million of our ordinary shares in this offering at the initial public offering price per share and on the same terms as the other purchasers in this offering. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could determine to sell more, fewer or no shares to any of these potential purchasers, and any of these potential purchasers could determine to purchase more, fewer or no shares in this offering. The underwriters will receive the same underwriting discount and commissions on these shares as they will on any other shares sold to the public in this offering.

#### The Offering

Ordinary shares offered by us 5,000,000 ordinary shares.

Ordinary shares to be outstanding after this offering 27,184,140 ordinary shares (or 27,934,140 shares if the underwriters exercise their option

to purchase additional ordinary shares in full).

Option to purchase additional shares

The underwriters have a 30-day option to purchase up to 750,000 additional ordinary

shares at the public offering price less estimated underwriting discounts and commissions.

Use of proceeds We estimate that the net proceeds from this offering will be approximately \$67.0 million

(or approximately \$77.5 million if the underwriters exercise their option to purchase additional ordinary shares in full), based on an assumed initial public offering price of \$15.00 per ordinary share, after deducting the estimated underwriting discounts and commissions and the estimated offering expenses payable by us. We anticipate that we will use the net proceeds of this offering to continue to develop our most advanced product candidates, AAV-CNGB3, AAV-CNGA3, AAV-RPGR, AAV-RPE65 and AAV-AQP1, scale-up our manufacturing facility and related processes, fund research and development of other pipeline product candidates and technologies, and the remainder, if any, to fund new and ongoing research and development activities and for working capital and other general corporate purposes as set forth under "Use of Proceeds" beginning on page 71.

Risk factors You should carefully read the "Risk Factors" beginning on page 12 and the other

information included in this prospectus for a discussion of factors you should consider  $% \left( 1\right) =\left( 1\right) \left( 1\right)$ 

carefully before deciding to invest in our ordinary shares.

Proposed Nasdaq Global Select Market symbol "MGTX"

The number of our ordinary shares to be outstanding after this offering is based on 9,376,360 ordinary shares outstanding as of April 30, 2018, including 22,777 unvested restricted shares subject to repurchase, and excludes:

- 1,614,346 ordinary shares issuable upon exercise of share options outstanding under our 2016 Equity Incentive Plan, referred to as our 2016 Plan, as of April 30, 2018, at a weighted-average exercise price of \$5.32 per ordinary share;
- 3,054,996 ordinary shares reserved for future issuance under our 2018 Incentive Award Plan, referred to as our 2018 Plan, which will become effective in connection with this offering, as well as any automatic increases in the number of our ordinary shares reserved for future issuance under our 2018 Plan; and
- 509,166 ordinary shares reserved for future issuance under our 2018 Employee Share Purchase Plan, referred to as our 2018 ESPP, which will become effective in connection with this offering, as well as any automatic increases in the number of our ordinary shares reserved for future issuance under our 2018 ESPP.

Unless otherwise indicated, this prospectus reflects and assumes the following:

- the Corporate Reorganization;
- other than in the consolidated financial statements and related notes thereto included elsewhere in this prospectus or as otherwise indicated, a 1 for 3.881 reverse share split of all outstanding ordinary shares (by way of consolidation of the share capital of the Company) and a corresponding adjustment to the conversion ratio for our outstanding preferred shares, which will be effective following the Corporate Reorganization and prior to the start of trading of the ordinary shares on the Nasdaq Global Select Market;
- the exercise of all outstanding warrants by the holders thereof for an aggregate of 927,594 preferred shares for an aggregate purchase price of \$9.7 million;
- the conversion of all of our preferred shares, including 927,594 preferred shares that will be issued as a result of the exercise of all outstanding warrants, into an aggregate of 11,501,432 ordinary shares prior to the closing of this offering;
- the issuance to Alexandria Forbes, Ph.D., our President and Chief Executive Officer, and Rich Giroux, our Chief Operating Officer of an aggregate of 1,306,348 ordinary shares, which number of shares assumes that we sell the number of shares set forth on the cover page of this prospectus in this offering, on the date the registration statement of which this prospectus forms a part becomes effective or, if later, on the date we file a registration statement on Form S-8 covering the issuance of the ordinary shares. 435,450 of these ordinary shares vest immediately and 870,898 will vest in eight equal quarterly installments beginning three months after effectiveness of this registration statement. These grants are referred to in this prospectus as the "Executive IPO Grants";
- no exercise of outstanding options after April 30, 2018; and
- · no exercise by the underwriters of their option to purchase additional ordinary shares in this offering.

Certain of our existing shareholders and their affiliated entities have indicated an interest in purchasing an aggregate of up to approximately \$40.0 million of our ordinary shares in this offering at the initial public offering price per share and on the same terms as the other purchasers in this offering. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could determine to sell more, fewer or no shares to any of these potential purchasers, and any of these potential purchasers could determine to purchase more, fewer or no shares in this offering. The underwriters will receive the same underwriting discount and commissions on these shares as they will on any other shares sold to the public in this offering.

# **Summary Consolidated Financial Data**

The following tables set forth our summary consolidated financial data for the period indicated. We have derived the consolidated statement of operations and comprehensive loss data for the years ended December 31, 2016 and 2017 from our audited consolidated financial statements included elsewhere in this prospectus. We have derived the consolidated balance sheet data as of March 31, 2018 and the consolidated statement of operations and comprehensive loss data for the three months ended March 31, 2017 and 2018 from our unaudited financial statements included elsewhere in this prospectus. These unaudited financial statements have been prepared on a basis consistent with our audited financial statements and, in our opinion, contain all adjustments, consisting of normal and recurring adjustments, necessary for the fair presentation of such financial data. Our historical results are not necessarily indicative of the results that should be expected for any future period. You should read the following summary consolidated financial data together with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and the related notes included elsewhere in this prospectus.

	Year Ended December 31,		Three Months Ended March 31,	
	2016	2017	2017	2018
Consolidated Statement of Operations and Comprehensive Loss				
Data:				
Operating expenses:				
General and administrative	\$ 6,026,529	\$ 9,325,017	\$ 2,148,540	\$ 11,122,016
Research and development	14,037,918	22,359,712	4,823,357	6,927,322
Total operating expenses	20,064,447	31,684,729	6,971,897	18,049,338
Loss from operations	(20,064,447)	(31,684,729)	(6,971,897)	(18,049,338)
Other non-operating income (expense):				
Foreign currency gain	265,543	1,676,117	149,249	978,624
Convertible note inducement expense	_	(553,500)	_	_
Change in fair value of warrant liability	_	(465,633)	_	669,408
Interest income	32,068	26,073	10,389	25,308
Interest expense	(25,440)	(42,863)	(8,126)	(27,355)
Net loss	(19,792,276)	(31,044,535)	(6,820,385)	(16,403,353)
Net loss attributable to non-controlling interest in subsidiary	305,883			
Net loss attributable to MeiraGTx shareholders	(19,486,393)	(31,044,535)	(6,820,385)	(16,403,353)
Other comprehensive loss	(671,391)	(1,361,365)	(130,895)	(757,765)
Comprehensive loss	(20,157,784)	(32,405,900)	(6,951,280)	(17,161,118)
Less: comprehensive loss (income) attributable to non-controlling				
interest	8,520	_	_	_
Comprehensive loss attributable to MeiraGTx shareholders	\$(20,149,264)	\$(32,405,900)	\$(6,951,280)	\$(17,161,118)
Net loss attributable to MeiraGTx shareholders	\$(19,486,393)	\$(31,044,535)	\$(6,820,385)	\$(16,403,353)
Accretion on Series C preferred shares	(85,425)	(806,963)	(22,761)	(664,718)
Adjusted net loss attributable to MeiraGTx ordinary shareholders	\$(19,571,818)	\$(31,851,498)	\$(6,843,146)	\$(17,068,071)

	Year Ended December 31, 2016 2017		Three Months Ended March 31, 2017 2018	
Basic and diluted net loss per ordinary share attributable to ordinary shareholders(1)	\$ (0.63)	\$ (0.96)	\$ (0.21)	\$ (0.49)
Weighted-average number of ordinary shares outstanding —basic and diluted(1)	31,098,591	33,269,157	32,851,408	34,647,368

(1) See Note 12 to our consolidated financial statements included elsewhere in this prospectus for an explanation of the method used to calculate the historical basic and diluted net loss per ordinary share and the weighted-average number of shares used in the computation of the per share amounts. Shares outstanding does not give effect to the anticipated 1 for 3.881 reverse stock split (by way of consolidation of the share capital of the Company) described elsewhere in this prospectus.

	As of March 31, 2018		
	Actual	Pro Forma(1)	Pro Forma As Adjusted(2)(3)
Consolidated Balance Sheet Data:	<u> </u>		
Cash and cash equivalents	\$ 32,356,851	\$54,464,388	\$ 121,464,388
Total assets	\$ 50,780,903	\$72,888,440	\$ 139,888,440
Total liabilities	\$ 14,345,189	\$12,334,964	\$ 18,866,714
Convertible preferred C shares	\$ 97,351,080	_	_
Total shareholders' (deficit) equity	\$(60,915,366)	\$60,553,476	\$ 121,021,741

- (1) The proforma data above gives effect to (a) the Corporate Reorganization described under "Summary—Corporate Reorganization", (b) the conversion of all outstanding preferred shares, including preferred shares issued in connection with the exercise of warrants for cash in an amount equal to \$9.7 million, into ordinary shares prior to the closing of this offering, (c) the reclassification of the related warrant liability into capital in excess of nominal value, and (d) our issuance of 4.7 million preferred shares in April 2018 for aggregate proceeds of \$12.7 million.
- (2) The pro forma as adjusted data above reflects (a) the pro forma adjustments described in footnote (1) above, (b) the issuance of the Executive IPO Grants plus the accrual of expenses in the amount of \$6.5 million, based on an assumed initial public offering price of \$15.00 per ordinary share, which is the midpoint of the price range set forth on the cover page of this prospectus, related to our obligation to pay associated income taxes incurred by the named executive officers in connection therewith (such \$6.5 million amount representing only one-third of our total obligation to pay income taxes incurred by the named executive officers upon vesting of the Executive IPO Grants, based on an assumed initial public offering price of \$15.00 per ordinary share, which is the midpoint of the price range set forth on the cover page of this prospectus) and (c) the issuance and sale of 5,000,000 ordinary shares in this offering at an assumed initial public offering price of \$15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.
- (3) The pro forma as adjusted information discussed above is illustrative only and will depend on the actual initial public offering price and other terms of our initial public offering determined at pricing. Each \$1.00 increase (decrease) in the assumed initial public offering price of \$15.00 per ordinary share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash and cash equivalents, total assets and total shareholders' equity by \$4.6 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase (decrease) of 1.0 million in the number of ordinary shares offered by us at the assumed initial public offering price would increase (decrease) each of cash and cash equivalents, total assets and total shareholders' equity by \$13.9 million, assuming that the assumed initial public offering price remains the same, and after deducting the estimated underwriting discounts and commissions and the estimated offering expenses payable by us.

#### RISK FACTORS

You should carefully consider the risks and uncertainties described below and the other information in this prospectus before making an investment in our ordinary shares. Our business, financial condition, results of operations or prospects could be adversely affected if any of these risks occurs, and as a result, the market price of our ordinary shares could decline and you could lose all or part of your investment. This prospectus also contains forward-looking statements that involve risks and uncertainties. See "Cautionary Statement Regarding Forward-Looking Statements." Our actual results could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including those set forth below.

#### Risks Related to Our Financial Position and Need for Additional Capital

We have incurred significant losses since inception and anticipate that we will incur continued losses for the foreseeable future, and may never achieve or maintain profitability.

We are a clinical stage company with limited operating history. We were formed and began operations in 2015 through the acquisition of Athena Vision Ltd. and certain assets from Kadmon Corporation, LLC. We have never been profitable and do not expect to be profitable in the foreseeable future. We have incurred net losses since inception, including net losses of approximately \$16.4 million and \$6.8 million for the three months ended March 31, 2018 and 2017, respectively, and approximately \$31.0 million and \$19.8 million for the years ended December 31, 2017 and December 31, 2016, respectively. As of March 31, 2018, we had an accumulated deficit of approximately \$81.8 million. Since our inception, we have devoted substantially all of our resources to developing our technology platform, establishing our viral vector manufacturing facility and developing manufacturing processes, advancing the product candidates in our ophthalmology, salivary gland and neurodegenerative disease programs, building our intellectual property portfolio, organizing and staffing our company, business planning, raising capital, and providing general and administrative support for these operations. We have not yet demonstrated an ability to successfully complete a clinical program, including large-scale, pivotal clinical trials, obtain marketing approval, manufacture product at a commercial scale, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Typically, it takes about six to ten years to develop a new drug from the time it enters Phase 1 clinical trials to when it is approved for treating patients, but in many cases it may take longer. Consequently, predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing genetic medicine products.

We expect to continue to incur significant expenses and additional operating losses for the foreseeable future as we seek to advance product candidates through preclinical and clinical development, expand our research and development activities, develop new product candidates, complete clinical trials, seek regulatory approval and, if we receive regulatory approval, commercialize our products. Furthermore, the costs of advancing product candidates into each succeeding clinical phase tend to increase substantially over time. The total costs to advance any of our product candidates to marketing approval in even a single jurisdiction would be substantial. Because of the numerous risks and uncertainties associated with gene therapy product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to begin generating revenue from the commercialization of products or achieve or maintain profitability. Our expenses will also increase substantially if and as we operate as a public company and add clinical, scientific, operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts, as well as to support our transition to a public reporting company.

Before we generate any revenue from product sales, each of our programs and product candidates will require additional preclinical and/or clinical development, potential regulatory approval in multiple jurisdictions, manufacturing, building of a commercial organization, substantial investment and significant marketing efforts. Our expenses could increase beyond expectations if we are required by the U.S. Food and Drug Administration, or FDA, European Medicines Agency, or EMA, or other regulatory authorities to perform preclinical studies and

clinical trials in addition to those that we currently anticipate. These risks are further described under "—Risks Related to Discovery, Development, Clinical Testing, Manufacturing and Regulatory Approval" and "—Risks Related to Commercialization." As a result, we expect to continue to incur net losses and negative cash flows for the foreseeable future. These net losses and negative cash flows have had, and will continue to have, an adverse effect on our shareholders' equity and working capital.

As we continue to build our business, we expect our financial condition and operating results may fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any particular quarterly or annual period as indications of future operating performance. If we are unable to develop and commercialize one or more of our product candidates either alone or with collaborators, or if revenues from any product candidate that receives marketing approval are insufficient, we will not achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability. If we are unable to achieve and then maintain profitability, the value of our equity securities will be adversely affected.

#### We will require additional capital to fund our operations, which may not be available on acceptable terms, if at all.

We expect to spend substantial amounts to complete the development of, seek regulatory approvals for and commercialize our product candidates. We will require additional capital beyond the proceeds of this offering, which we may raise through equity offerings, debt financings, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements or other sources to enable us to complete the development and potential commercialization of our product candidates. Furthermore, upon the closing of this offering, we expect to incur additional costs associated with operating as a public company. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative effect on our financial condition and our ability to pursue our business strategy. In addition, attempting to secure additional financing may divert the time and attention of our management from day-to-day activities and harm our product candidate development efforts. If we are unable to raise capital when needed or on acceptable terms, we would be forced to delay, reduce or eliminate certain of our research and development programs.

Our operations have consumed significant amounts of cash since inception. As of March 31, 2018, our cash and cash equivalents were \$32.4 million. Based on our planned use of the net proceeds of this offering and our current cash and cash equivalents, we estimate that such funds will be sufficient to enable us to fund our operating expenses and capital expenditure requirements through the third quarter of 2020. This estimate is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Changing circumstances could cause us to consume capital significantly faster than we currently anticipate, and we may need to spend more than currently expected because of circumstances beyond our control. Because the length of time and activities associated with successful development of our product candidates is highly uncertain, we are unable to estimate the actual funds we will require for development and any approved marketing and commercialization activities. Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the progress, timing, costs and results of our ongoing clinical development for our *CNGB3* gene therapy product candidate, AAV-CNGB3, for our *RPE65*-deficiency product candidate, AAV-RPE65, for our X-linked retinitis pigmentosa product candidate, AAV-RPGR, for our radiation induced xerostomia product candidate, AAV-AQP1, and continue to conduct our ongoing natural history studies for inherited retinal diseases, or IRDs;
- the initiation of Phase 1/2 clinical trials for our *CNGA3* gene therapy product candidate, AAV-CNGA3, and for our product candidate for the treatment of xerostomia associated with Sjogren's syndrome, AAV-AQP1;

- continuing our current research programs, our preclinical development of product candidates from our current research programs and further developing our gene regulation technology;
- seeking to identify, assess, acquire and/or develop additional research programs and additional product candidates;
- the preclinical testing and clinical trials for any product candidates we identify and develop;
- establishing a sales, marketing and distribution infrastructure to commercialize any product candidates for which we may obtain marketing approval;
- · the outcome, timing and cost of meeting regulatory requirements established by the FDA, EMA and other regulatory authorities;
- the cost of expanding and protecting our intellectual property portfolio, including filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- the cost of defending potential intellectual property disputes, including patent infringement actions brought by third parties against us or any of our product candidates;
- the effect of competing technological and market developments;
- the cost of further developing and scaling our manufacturing facility and processes;
- the cost and timing of completion of commercial-scale manufacturing activities;
- the cost of making royalty, milestone or other payments under current and any future in-license agreements;
- the extent to which we in-license or acquire other products and technologies;
- the cost of establishing sales, marketing and distribution capabilities for our product candidates in regions where we choose to commercialize our products; and
- · the initiation, progress, timing and results of our commercialization of our product candidates, if approved for commercial sale.

We cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of our product candidates or potentially discontinue operations.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common shareholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

We are heavily dependent on the success of our most advanced product candidates, AAV-CNGB3, AAV-CNGA3, AAV-RPGR, AAV-RPE65 and AAV-AQP1, which are still in development, and if none of them receive regulatory approval or are successfully commercialized, our business may be harmed.

To date, we have invested a significant portion of our efforts and financial resources in the development of AAV-CNGB3, AAV-CNGA3, AAV-RPGR, AAV-RPE65 and AAV-AQP1. Our future success and ability to generate product revenue is substantially dependent on our ability to successfully develop, obtain regulatory approval for and successfully commercialize these product candidates. We currently have no products that are approved for commercial sale and may never be able to develop marketable products. We expect to invest a meaningful portion of our efforts and expenditures over the next few years in AAV-CNGB3, AAV-CNGA3, AAV-RPGR, AAV-RPE65 and AAV-AQP1, which will require additional clinical development, management of clinical and manufacturing activities, regulatory approval in multiple jurisdictions, manufacturing sufficient supply, building of a commercial organization, substantial investment and significant marketing efforts before we can generate any revenues from any commercial sales. Accordingly, our business currently depends heavily on the successful development, regulatory approval and commercialization of AAV-CNGB3, AAV-CNGA3, AAV-RPGR, AAV-RPE65 and AAV-AQP1, which may never occur. We cannot be certain that AAV-CNGB3, AAV-CNGA3, AAV-RPGR, AAV-RPE65 or AAV-AQP1 will be successful in clinical trials, receive regulatory approval or be successfully commercialized even if we receive regulatory approval. Even if we receive approval to market AAV-CNGB3, AAV-CNGA3, AAV-RPGR, AAV-RPE65 or AAV-AQP1 from the FDA, EMA or other regulatory bodies, we cannot be certain that our product candidate will be successfully commercialized, widely accepted in the marketplace or more effective than other commercially available alternatives. Additionally, the research, testing, manufacturing, labeling, approval, sale, marketing and distribution of gene therapy products are and will remain subject to extensive and evolving regulation by the FDA, EMA and other regulatory authorities. We are not permitted to market AAV-CNGB3, AAV-RPGR, AAV-RPE65 or AAV-AQP1 in the United States until they receive approval of a biologics license application, or BLA, from the FDA, and we cannot market them in the European Union until we receive approval for a Marketing Authorization Application, or MAA, from the EMA, or other required regulatory approval in other countries.

AAV-CNGB3, AAV-CNGA3, AAV-RPGR, AAV-RPE65 and AAV-AQP1 are our most advanced product candidates, and because some of our other product candidates are based on similar technology, if AAV-CNGB3, AAV-CNGA3, AAV-RPGR, AAV-RPE65 or AAV-AQP1 show unexpected adverse events or a lack of efficacy in the indications we intend to treat, or if we experience other regulatory or developmental issues, our development plans and business could be significantly harmed. Further, competitors may be developing products with similar technology and may experience problems with their products that could identify problems that would potentially harm our business.

# We may not be successful in our efforts to identify additional product candidates.

Part of our strategy involves identifying novel product candidates. The process by which we identify product candidates may fail to yield product candidates for clinical development for a number of reasons, including those discussed in these risk factors and also:

- we may not be able to assemble sufficient resources to acquire or discover additional product candidates;
- competitors may develop alternatives that render our potential product candidates obsolete or less attractive;
- · potential product candidates we develop may nevertheless be covered by third parties' patents or other exclusive rights;
- potential product candidates may, on further study, be shown to have harmful side effects, toxicities or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance;

- potential product candidates may not be effective in treating their targeted diseases;
- the market for a potential product candidate may change so that the continued development of that product candidate is no longer reasonable;
- a potential product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; or
- the regulatory pathway for a potential product candidate is too complex and difficult to navigate successfully or economically.

In addition, we may choose to focus our efforts and resources on a potential product candidate that ultimately proves to be unsuccessful. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other product candidates or other diseases that may later prove to have greater commercial potential, or relinquish valuable rights to such product candidates through collaboration, licensing or other royalty arrangements in cases in which it would have been advantageous for us to retain sole development and commercialization rights. If we are unable to identify additional suitable product candidates for clinical development, this would adversely impact our business strategy and our financial position and share price and could potentially cause us to cease operations.

Management concluded that factors raise substantial doubt about our ability to continue as a going concern and our independent registered public accounting firm has included an explanatory paragraph relation to our ability to continue as a going concern in its report on our audited consolidated financial statements included in this prospectus.

Our consolidated financial statements at December 31, 2016 and 2017 and March 31, 2017 and 2018 and for the periods then ended were prepared assuming that we will continue as a going concern and accordingly the accompanying financial statements do not include any adjustments that might be necessary should we be unable to continue as a going concern. However, we do not have adequate cash on hand to fund our anticipated expenses past the next 12 months without obtaining significant additional financing. This raises substantial doubt about our ability to continue as a going concern. Such determination could materially limit our ability to raise additional funds through the issuance of new debt or equity securities or otherwise. There is no assurance that sufficient financing will be available when needed to allow us to continue as a going concern. The perception that we may not be able to continue as a going concern may also make it more difficult to operate our business due to concerns about our ability to meet our contractual obligations. Our ability to continue as a going concern is contingent upon, among other factors, the sale of ordinary shares in this offering or obtaining alternate financing. We cannot provide any assurance that we will be able to raise additional capital. If we are unable to secure additional capital, we may be required to curtail our research and development initiatives and take additional measures to reduce costs in order to conserve our cash in amounts sufficient to sustain operations and meet our obligations. These measures could cause significant delays in our clinical efforts, which is critical to the realization of our business plan. It is not possible for us to predict at this time the potential success of our business. The revenue and income potential of our proposed business and operations are currently unknown. If we cannot continue as a viable entity, you may lose some or all of your investment.

In addition, the report of our independent registered public accounting firm with respect to our consolidated financial statements appearing elsewhere in this prospectus contains an explanatory paragraph stating the Company has suffered recurring losses from operations, is subject to significant uncertainty with respect to its product development and has stated that substantial doubt exists about the Company's ability to continue as a going concern Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 1 to the consolidated financial statements.

#### Risks Related to Discovery, Development, Clinical Testing, Manufacturing and Regulatory Approval

We intend to identify and develop product candidates based on our novel gene therapy platform, which makes it difficult to predict the time and cost of product candidate development. Very few products that utilize transduction technology have been approved in the United States or in Europe, and there have only been a limited number of clinical trials involving a gene therapy product candidate.

We have concentrated a portion of our research and development efforts on our gene therapy platform, which uses both transduction and gene regulation technology. Our future success depends on the successful development of these novel therapeutic approaches. To date, very few products that utilize gene transfer have been approved in the United States or Europe. There have been a limited number of clinical trials of gene transduction technologies, with only one product candidate ever approved by the FDA.

Our gene therapy platform is based on a suite of viral vectors which we can deploy with gene therapy constructs, which relies on the ability of AAV to efficiently transmit a therapeutic gene to certain kinds of cells. The mechanism of action by which these vectors target particular tissues is still not completely understood. Therefore, it is difficult for us to determine that our vectors will be able to properly deliver gene transfer constructs to, enough tissue cells to reach therapeutic levels. We cannot be certain that our viral vectors will be able to meet safety and efficacy levels needed to be therapeutic in humans or that they will not cause significant adverse events or toxicities. Furthermore, recent work conducted by a third party in non-human primates suggests that intravenous delivery of certain AAV vectors at very high doses may result in severe toxicity. The indications that we target do not use IV administration for viral vector delivery and do not use doses as high as those tested in these publications, and to date we have not observed the severe toxicities described in these publications with the naturally occurring AAV vectors that we use. However, we cannot be certain that we will be able to avoid triggering toxicities in our future preclinical studies or clinical trials. Any such results could impact our ability to develop a product candidate. As a result of these factors, it is more difficult for us to predict the time and cost of product candidate development, and we cannot predict whether the application of our gene therapy platform, or any similar or competitive gene therapy platforms, will result in the identification, development, and regulatory approval of any product candidates, or that other gene therapy technologies will not be considered better or more attractive. There can be no assurance that any development problems we experience in the future related to our gene therapy platform or any of our research programs will not cause significant delays or unanticipated costs, or that such development problems can be solved. We may also experience delays and challenges in utilizing our manufacturing facility and achieving sustainable, reproducible, and scalable production. Any of these factors may prevent us from completing our preclinical studies or clinical trials or commercializing any product candidates we may develop on a timely or profitable basis, if at

In addition, because our gene regulation technology is still in the research stage, we have not yet been able to assess safety in humans, and there may be long-term effects from treatment that we cannot predict at this time. Also, animal models may not exist for some of the diseases we expect to pursue.

Because gene therapy is novel and the regulatory landscape that governs any product candidates we may develop is uncertain and may change, we cannot predict the time and cost of obtaining regulatory approval, if we receive it at all, for any product candidates we may develop.

The regulatory requirements that will govern any novel gene therapy product candidates we develop are not entirely clear and may change. Within the broader genetic medicine field, very few therapeutic products have received marketing authorization from the EMA and FDA. Even with respect to more established products that fit into the categories of gene therapies or cell therapies, the regulatory landscape is still developing. Regulatory requirements governing gene therapy products and cell therapy products have changed frequently and will likely continue to change in the future. Moreover, there is substantial, and sometimes uncoordinated, overlap in those responsible for regulation of existing gene therapy products and cell therapy products. For example, in the United States, the FDA has established the Office of Tissues and Advanced Therapies within its Center for Biologics Evaluation and Research, or CBER, to consolidate the review of gene therapy and related products, and the

Cellular, Tissue and Gene Therapies Advisory Committee to advise CBER on its review. Gene therapy clinical trials are also subject to review and oversight by an institutional biosafety committee, or IBC, a local institutional committee that reviews and oversees basic and clinical research conducted at the institution participating in the clinical trial. Gene therapy clinical trials conducted at institutions that receive funding for recombinant DNA research from the United States National Institutes of Health, or the NIH, are also subject to review by the NIH Office of Biotechnology Activities' Recombinant DNA Advisory Committee. Although the FDA decides whether individual gene therapy protocols may proceed, the review process and determinations of other reviewing bodies can impede or delay the initiation of a clinical trial, even if the FDA has reviewed the trial and approved its initiation. The same applies in the European Union. The EMA's Committee for Advanced Therapies, or CAT, is responsible for assessing the quality, safety, and efficacy of advanced-therapy medicinal products. Advanced-therapy medicinal products include gene therapy medicines, somatic-cell therapy medicines and tissue-engineered medicines. The role of the CAT is to prepare a draft opinion on an application for marketing authorization for a gene therapy medicinal candidate that is submitted to the EMA. In the European Union, the development and evaluation of a gene therapy product must be considered in the context of the relevant EU guidelines. The EMA may issue new guidelines concerning the development and marketing authorization for gene therapy products and require that we comply with these new guidelines. As a result, the procedures and standards applied to gene therapy products and cell therapy products may be applied to any gene therapy product candidate we may develop, but that remains uncertain at this point.

Adverse developments in preclinical studies or clinical trials conducted by others in the field of gene therapy and gene regulation products may cause the FDA, the EMA, and other regulatory bodies to revise the requirements for approval of any product candidates we may develop or limit the use of products utilizing gene regulation technologies, either of which could harm our business. In addition, the clinical trial requirements of the FDA, the EMA, and other regulatory authorities and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty, and intended use and market of the potential products. The regulatory approval process for product candidates such as ours can be more expensive and take longer than for other, better known, or more extensively studied pharmaceutical or other product candidates. Further, as we are developing novel treatments for diseases in which there is little clinical experience with new endpoints and methodologies, there is heightened risk that the FDA, the EMA or other regulatory bodies may not consider the clinical trial endpoints to provide clinically meaningful results, and the resulting clinical data and results may be more difficult to analyze. The prospectively designed natural history studies with the same endpoints as our corresponding clinical trials may not be accepted by the FDA, EMA or other regulatory authorities. Regulatory agencies administering existing or future regulations or legislation may not allow production and marketing of products utilizing gene regulation technology in a timely manner or under technically or commercially feasible conditions. In addition, regulatory action or private litigation could result in expenses, delays, or other impediments to our research programs or the commercialization of resulting products.

The regulatory review committees and advisory groups described above and the new guidelines they promulgate may lengthen the regulatory review process, require us to perform additional preclinical studies or clinical trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of these treatment candidates, or lead to significant post-approval limitations or restrictions. As we advance our research programs and develop future product candidates, we will be required to consult with these regulatory and advisory groups and to comply with applicable guidelines. If we fail to do so, we may be required to delay or discontinue development of any product candidates we identify and develop.

Clinical trials are expensive, time-consuming, difficult to design and implement, and involve an uncertain outcome. Further, we may encounter substantial delays in our clinical trials.

The clinical trials and manufacturing of our product candidates are, and the manufacturing and marketing of our products, if approved, will be, subject to extensive and rigorous review and regulation by numerous government authorities in the United States and in other countries where we intend to test and market our product candidates. Before obtaining regulatory approvals for the commercial sale of any of our product

candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are both safe and effective for use in each target indication. In particular, because our product candidates are subject to regulation as biological drug products, we will need to demonstrate that they are safe, pure, and potent for use in their target indications. Each product candidate must demonstrate an adequate risk versus benefit profile in its intended patient population and for its intended use.

Clinical testing is expensive and can take many years to complete, and subject to uncertainty. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. Failure can occur at any time during the clinical trial process. Even if our future clinical trials are completed as planned, we cannot be certain that their results will support the safety and effectiveness of our product candidates for their targeted indications. Our future clinical trial results may not be successful.

In addition, even if such trials are successfully completed, we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit our product candidates for approval. To the extent that the results of the trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates.

To date, we have not completed any clinical trials required for the approval of our product candidates. Although we have already begun Phase 1/2 clinical trials, we may experience delays in conducting any clinical trials and we do not know whether our clinical trials will begin on time, need to be redesigned, recruit and enroll patients on time or be completed on schedule, or at all. Events that may prevent successful or timely completion of clinical development include:

- inability to generate sufficient preclinical, toxicology, or other in vivo or in vitro data to support the initiation of clinical trials;
- · delays in sufficiently developing, characterizing or controlling a manufacturing process suitable for advanced clinical trials;
- delays in developing suitable assays for screening patients for eligibility for trials with respect to certain product candidates;
- delays in reaching agreement with the FDA, EMA or other regulatory authorities as to the design or implementation of our clinical trials:
- obtaining regulatory approval to commence a clinical trial;
- reaching an agreement on acceptable terms with clinical trial sites or prospective CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different clinical trial sites;
- · obtaining institutional review board, or IRB, approval at each site;
- recruiting suitable patients to participate in a clinical trial;
- developing and validating the companion diagnostic to be used in a clinical trial, if applicable;
- having patients complete a clinical trial or return for post-treatment follow-up;
- clinical sites, contract research organizations, or other third parties deviating from trial protocol or dropping out of a trial;
- failure to open the IND for AAV-CNGA3 because of the clinical hold put in place by the FDA;
- failure to perform in accordance with the FDA's good clinical practice, or GCP, requirements, or applicable regulatory guidelines in other countries;

- addressing patient safety concerns that arise during the course of a trial, including occurrence of adverse events associated with the
  product candidate that are viewed to outweigh its potential benefits;
- · adding a sufficient number of clinical trial sites; or
- manufacturing sufficient quantities of product candidate for use in clinical trials.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates or significantly increase the cost of such trials, including:

- we may experience changes in regulatory requirements or guidance, or receive feedback from regulatory authorities that requires us to modify the design of our clinical trials;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we or our investigators might have to suspend or terminate clinical trials of our product candidates for various reasons, including non-compliance with regulatory requirements, a finding that our product candidates have undesirable side effects or other unexpected characteristics, or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate and we may not have funds to cover the costs;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;
- regulators may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate; and
- any future collaborators that conduct clinical trials may face any of the above issues, and may conduct clinical trials in ways they view
  as advantageous to them but that are suboptimal for us.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- incur unplanned costs;
- · be delayed in obtaining marketing approval for our product candidates or not obtain marketing approval at all;
- obtain marketing approval in some countries and not in others;
- obtain marketing approval for indications or patient populations that are not as broad as intended or desired;

- obtain marketing approval with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings;
- be subject to additional post-marketing testing requirements; or
- have the product removed from the market after obtaining marketing approval.

We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by the Data Safety Monitoring Board, or DSMB, for such trial or by the FDA, EMA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA, EMA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. For example, our IND for AAV-RPE65 was filed in July 2017. On August 16, 2017, we received notification from the FDA supporting the use of the described batches of product candidate in the Phase 1/2 clinical trial. However, we received a recommendation from the FDA on a certain aspect of the manufacturing process for future clinical trials, thus putting our IND for AAV-RPE65 on partial clinical hold. We responded to the FDA on October 2, 2017 and, based on this response, the partial clinical hold was lifted on October 17, 2017. As another example, our IND for AAV-CNGB3 was filed on October 31, 2017. We received a question from the FDA around our injection device compatibility assay, thus putting our AAV-CNGB3 IND on clinical hold. In the device compatibility assay, the FDA noted a disparity between the target titer for the intended low dose dilution and the actual titer obtained on polymerase chain reaction, or PCR, analysis. The FDA requested clarification on whether this was an imprecise dilution scheme for the low dose or a PCR assay issue. We submitted our second response to the FDA on May 2, 2018 providing data that identified the issue as a PCR assay artifact and also s

Our most advanced product candidates, AAV-CNGB3, AAV-CNGA3, AAV-RPGR, AAV-RPE65 and AAV-AQP1, will require extensive clinical testing before we are prepared to submit a BLA or MAA for regulatory approval. We cannot predict with any certainty if or when we might complete the clinical development for our product candidates and submit a BLA or MAA for regulatory approval of any of our product candidates or whether any such BLA or MAA will be approved. We may also seek feedback from the FDA, EMA or other regulatory authorities on our clinical development program, and the FDA, EMA or such regulatory authorities may not provide such feedback on a timely basis, or such feedback may not be favorable, which could further delay our development programs.

If we experience delays in the commencement or completion of our clinical trials, or if we terminate a clinical trial prior to completion, the commercial prospects of our product candidates could be harmed, and our ability to generate revenues from our product candidates may be delayed. In addition, any delays in our clinical trials could increase our costs, slow down the development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and results of operations. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

The affected populations for our other product candidates may be smaller than we or third parties currently project, which may affect the addressable markets for our product candidates.

Our projections of the number of people who have the diseases we are seeking to treat, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, are estimates based on our knowledge and understanding of these diseases. The total addressable

market opportunity for our product candidates will ultimately depend upon a number of factors including the diagnosis and treatment criteria included in the final label, if approved for sale in specified indications, acceptance by the medical community, patient access and product pricing and reimbursement. Incidence and prevalence estimates are frequently based on information and assumptions that are not exact and may not be appropriate, and the methodology is forward-looking and speculative. The process we have used in developing an estimated incidence and prevalence range for the indications we are targeting has involved collating limited data from multiple sources. Accordingly, the incidence and prevalence estimates included in this prospectus should be viewed with caution. Further, the data and statistical information used in this prospectus, including estimates derived from them, may differ from information and estimates made by our competitors or from current or future studies conducted by independent sources.

The use of such data involves risks and uncertainties and is subject to change based on various factors. Our estimates may prove to be incorrect and new studies may change the estimated incidence or prevalence of the diseases we seek to address. The number of patients with the diseases we are targeting in the United States, the European Union and elsewhere may turn out to be lower than expected or may not be otherwise amenable to treatment with our products, or new patients may become increasingly difficult to identify or access, all of which would harm our results of operations and our business.

Negative public opinion of gene therapy and increased regulatory scrutiny of gene therapy and genetic research may adversely impact public perception of our current and future product candidates.

Our potential therapeutic products involve introducing genetic material into patient's cells. The clinical and commercial success of our potential products will depend in part on public acceptance of the use of gene therapy and gene regulation for the prevention or treatment of human diseases. Public attitudes may be influenced by claims that gene therapy and gene regulation are unsafe, unethical, or immoral, and, consequently, our products may not gain the acceptance of the public or the medical community. Adverse public attitudes may adversely impact our ability to enroll clinical trials. Moreover, our success will depend upon physicians prescribing, and their patients being willing to receive, treatments that involve the use of product candidates we may develop in lieu of, or in addition to, existing treatments with which they are already familiar and for which greater clinical data may be available.

More restrictive government regulations or negative public opinion would have a negative effect on our business or financial condition and may delay or impair the development and commercialization of our product candidates or demand for any products once approved. For example, in 2003, trials using early versions of murine gamma-retroviral vectors, which integrate with, and thereby alter, the host cell's DNA, have led to several well-publicized adverse events, including reported cases of leukemia. Although none of our current product candidates utilize murine gamma-retroviral vectors, our product candidates use a viral delivery system. Adverse events in our clinical trials, even if not ultimately attributable to our product candidates, and the resulting publicity could result in increased governmental regulation, unfavorable public perception, potential regulatory delays in the testing or approval of our product candidates, stricter labeling requirements for those product candidates that are approved and a decrease in demand for any such product candidates. The risk of cancer remains a concern for gene therapy and we cannot assure that it will not occur in any of our planned or future clinical trials. In addition, there is the potential risk of delayed adverse events following exposure to gene therapy products due to persistent biological activity of the genetic material or other components of products used to carry the genetic material. If any such adverse events occur, commercialization of our product candidates or further advancement of our clinical trials could be halted or delayed, which would have a negative impact on our business and operations.

Even though we have been granted access to the PRIME scheme by the EMA for AAV-CNGB3 and the FDA granted Fast Track designation to AAV-RPGR, in the future we may seek and fail to obtain access to the PRIME scheme by the EMA or fast track designation by the FDA for other of our current or potential future product candidates. We may also seek and fail to obtain breakthrough therapy designation from the FDA for our current or any future product candidates. Such designations or access may also not lead to faster development or regulatory review or approval, and it does not increase the likelihood that our product candidates will receive marketing approval.

A sponsor may seek approval of its product candidate under programs designed to accelerate FDA's review and approval of new drugs and biological products that meet certain criteria. For example, the FDA has a Fast Track program that is intended to expedite or facilitate the process for reviewing new products that meet certain criteria. Specifically, new drugs and biological products are eligible for Fast Track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs, or if the drug has been designated as a qualified infectious disease product. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. Under Fast Track, the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted if relevant criteria are satisfied, including an agreement with FDA on the proposed schedule for the submission of portions of the BLA, and the payment of applicable user fees before FDA may initiate a review. Even if Fast Track designation is granted, it may be rescinded if the product no longer meets the qualifying criteria. In April 2018, AAV-RPGR was designated a Fast Track program by the FDA for the treatment of X-linked retinitis pigmentosa owing to defects in RPGR.

In 2012, the Food and Drug Administration Safety and Innovation Act, or FDASIA, established the breakthrough therapy designation. A sponsor may seek FDA designation of its product candidate as a breakthrough therapy if the product candidate is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product candidate may demonstrate substantial improvement over existing therapies on one or more clinically-significant endpoints, such as substantial treatment effects observed early in clinical development. Sponsors may request that FDA designate a product candidate as a breakthrough therapy at the time of or any time after the submission of an IND, but ideally before an end-of-phase II meeting with FDA. If the FDA designates a breakthrough therapy, it may take actions appropriate to expedite the development and review of the application, which may include but are not limited to holding meetings with the sponsor and the review team throughout the development of the therapy; providing timely advice to, and interactive communication with, the sponsor regarding the development of the product candidate to ensure collection of appropriate data needed to support approval; more frequent written correspondence from the FDA about such things as the design of the proposed clinical trials and use of biomarkers; intensive guidance on an efficient drug development program, beginning as early as Phase 1; organizational commitment involving senior managers; and eligibility for rolling review and priority review. Breakthrough therapy designation comes with all of the benefits of fast track designation, which means that the sponsor may file sections of the BLA for review on a rolling basis if certain conditions are satisfied, including an agreement with FDA on the proposed schedule for submission of portions of the application and the payment of applicable user fees before the FDA may initiate a revi

Similarly, the EMA has established the PRIME scheme to expedite the development and review of product candidates that show a potential to address to a significant extent an unmet medical need, based on early clinical data. In February 2018, AAV-CNGB3 in the treatment of achromatopsia associated with defects in CNGB3 was admitted to the PRIME scheme of the EMA.

Fast Track designation and designation as a breakthrough therapy are within the discretion of the FDA. Accordingly, even if we believe one of our other product candidates meets the criteria for Fast Track designation or designation as a breakthrough therapy and we seek such designation, the FDA may disagree and instead

determine not to make such designation for such product candidate. We cannot be sure that our evaluation of our product candidates as qualifying for Fast Track designation or breakthrough therapy designation will meet the FDA's expectations. In any event, the receipt of a Fast Track designation or breakthrough therapy designation for a product candidate may not result in a faster development process, review, or approval compared to product candidates considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if additional product candidates are granted Fast Track designation or one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that such product candidates no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. Similarly, access to the PRIME scheme is at the discretion of the EMA, and we cannot be sure that any additional current or future product candidates will be granted access to the scheme; that participation in the scheme will result in expedited regulatory review or approval of our product candidates; or that access to the scheme, once granted, will not be revoked.

We have received orphan drug designation from the FDA and EMA for AAV-CNGB3, AAV-RPE65, AAV-RPGR, AAV-AIPL1 and FDA for AAV-AQP1 and may seek orphan drug designation for additional product candidates in the future, but any orphan drug designations we have received or may receive in the future may not confer marketing exclusivity or other expected benefits.

Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is intended to treat a rare disease or condition, defined as one occurring in a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the European Union, the EMA's Committee for Orphan Medicinal Products grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the European Union. Additionally, designation is granted for products intended for the diagnosis, prevention, or treatment of a life-threatening, seriously debilitating, or serious and chronic condition when, without incentives, it is unlikely that sales of the drug in the European Union would be sufficient to justify the necessary investment in developing the drug or biological product or where there is no satisfactory method of diagnosis, prevention, or treatment, or, if such a method exists, the medicine must be of significant benefit to those affected by the condition.

In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax credits for qualified clinical testing, and user-fee waivers. In addition, if a product receives the first FDA approval of that drug for the indication for which it has orphan designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity or where the manufacturer is unable to assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the rare disease or condition. Under the FDA's regulations, the FDA will deny orphan drug exclusivity to a designated drug upon approval if the FDA has already approved another drug with the same active ingredient for the same indication, unless the drug is demonstrated to be clinically superior to the previously approved drug. In the European Union, orphan drug designation entitles a party to financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity following approval for the approved therapeutic indication. This period may be reduced to six years if, at the end of the fifth year, the orphan drug designation criteria are no longer met, including where it is shown that the drug is sufficiently profitable not to justify maintenance of market exclusivity. In the European Union, a marketing authorization for an orphan designated product will not be granted if a similar drug has been approved in the European Union for the same therapeutic indication, unless the applicant can establish that its product is safer, more effective or otherwise clinically superior. A similar drug is a product containing a similar active substance or substances as those contained in an already authorized product. Similar active substance is defined as an identical active substance, or an active substance with the same principal molecular structural features (but not necessarily all of the same molecular features) and which acts via the same mechanism.

We have obtained orphan drug designation from the FDA and European Commission for AAV-CNGB3 for the treatment of achromatopsia caused by mutations in the CNGB3 gene, AAV-RPE65 for the treatment of Leber congenital amaurosis, AAV-RPGR for the treatment of retinitis pigmentosa and AAV-AIPL1 for the treatment of inherited retina dystrophy due to defects in AIPL1 gene, and we obtained orphan drug designation from the FDA for AAV-AQP1 for the treatment of grade 2 and grade 3 late xerostomia from parotid gland hypofunction caused by radiotherapy. We plan to seek orphan drug designation for other current and future product candidates. Even with orphan drug designation, we may not be the first to obtain marketing approval for any particular orphan indication due to the uncertainties associated with developing pharmaceutical products, which could prevent us from marketing our product candidates if another company is able to obtain orphan drug exclusivity before we do. In addition, exclusive marketing rights in the United States may be unavailable if we seek approval for an indication broader than the orphan-designated indication or may be lost in the United States if the FDA later determines that the request for designation was materially defective or if we are unable to assure sufficient quantities of the drug to meet the needs of patients with the rare disease or condition following approval. Further, even if we obtain orphan drug exclusivity, that exclusivity may not effectively protect our product candidates from competition because different drugs with different active moieties can be approved for the same condition. In addition, the FDA and the EMA can subsequently approve products with the same active moiety for the same condition if the FDA or the EMA concludes that the later drug is safer, more effective, or makes a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. In addition, while we intend to seek orphan drug designation for other existing and future product candidates, we may never receive such designations. There have been legal challenges to aspects of the FDA's regulations and policies concerning the exclusivity provisions of the Orphan Drug Act, and future challenges could lead to changes that affect the protections afforded our product candidates in ways that are difficult to predict. In 2014, a U.S. district court invalidated the FDA's denial of orphan exclusivity to an orphan designated drug, which the FDA had based on its determination that the drug was not proven to be clinically superior to a previously approved "same drug." In response to the decision, the FDA released a policy statement stating that the court's decision is limited to the facts of that particular case and that the FDA will continue to deny orphan drug exclusivity to a designated drug upon approval if the drug is the "same" as a previously approved drug, unless the drug is demonstrated to be clinically superior to that previously approved drug. Since then, similar legal challenges have been initiated against the FDA for its denial of orphan drug exclusivity to other designated drugs, and in 2017, Congress amended the Orphan Drug Act to require a demonstration of clinical superiority upon approval as a condition of receiving orphan drug exclusivity when another "same drug" has already been approved for the same indication. In the future, there is the potential for additional legal challenges to the FDA's orphan drug regulations and policies, and it is uncertain how ongoing and future challenges might affect our business.

We and our contract manufacturer for plasmid are subject to significant regulation with respect to manufacturing our products. Our manufacturing facilities and the third-party manufacturing facility which we rely on may not continue to meet regulatory requirements and have limited capacity.

We currently have relationships with a limited number of suppliers for the manufacturing of plasmid, a component of our viral vectors and product candidates. We completed the fit-out of our cGMP manufacturing facility in early 2018. However, if we experience slowdowns or problems with our facility and are unable to establish or scale our internal manufacturing capabilities, we will need to continue to contract with manufacturers that can produce the preclinical, clinical and commercial supply of our products. Each supplier may require licenses to manufacture such components if such processes are not owned by the supplier or in the public domain and we may be unable to transfer or sublicense the intellectual property rights we may have with respect to such activities.

All entities involved in the preparation of therapeutics for clinical trials or commercial sale, including our existing contract manufacturers for components our product candidates, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical trials in

the European Union must be manufactured in accordance with cGMP. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. We or our contract manufacturers must supply all necessary documentation in support of a BLA or MAA on a timely basis. Our facilities and quality systems and the facilities and quality systems of some or all of our third-party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our product candidates or any of our other potential products. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or our other potential products or the associated quality systems for compliance with the regulations applicable to the activities being conducted. If these facilities do not pass a pre-approval plant inspection, FDA approval of the products will not be granted.

The regulatory authorities also may, at any time following approval of a product for sale, audit our manufacturing facilities or those of our third-party contractors. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and/or time-consuming for us or a third party to implement and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could harm our business. If we or any of our third-party manufacturers fail to maintain regulatory compliance, the FDA can impose regulatory sanctions including, among other things, refusal to approve a pending application for a new drug product or biologic product, or revocation of a pre-existing approval. As a result, our business, financial condition and results of operations may be harmed. Additionally, if supply from one approved manufacturer is interrupted, there could be a significant disruption in commercial supply. An alternative manufacturer would need to be qualified through a BLA and/or MAA supplement which could result in further delay. The regulatory agencies may also require additional studies if a new manufacturer is relied upon for commercial production. Switching manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

These factors could cause the delay of clinical trials, regulatory submissions, required approvals or commercialization of our product candidates, cause us to incur higher costs and prevent us from commercializing our products successfully. Furthermore, if our suppliers fail to meet contractual requirements, and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical trials may be delayed or we could lose potential revenue.

Any contamination in our manufacturing process, shortages of raw materials or failure of our plasmid supplier to deliver necessary components could result in delays in our clinical development or marketing schedules.

Given the nature of biologics manufacturing, there is a risk of contamination. Any contamination could adversely affect our ability to produce product candidates on schedule and could, therefore, harm our results of operations and cause reputational damage. Some of the raw materials required in our manufacturing process are derived from biologic sources. Such raw materials are difficult to procure and may be subject to contamination or recall. A material shortage, contamination, recall or restriction on the use of biologically derived substances in the manufacture of our product candidates could adversely impact or disrupt the commercial manufacturing or the production of clinical material, which could adversely affect our development timelines and our business, financial condition, results of operations and prospects.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. The natural history studies may fail to provide us with patients for our clinical trials because patients enrolled in the natural history studies may not be good candidates for our clinical trials, or may choose to not enroll in our clinical trials. We may encounter delays in enrolling, or be unable to enroll, a sufficient number of patients to complete any of our clinical trials, and even once enrolled we may be unable to retain a sufficient number of patients to complete any of our trials. The enrollment of patients depends on many factors, including:

- the size and nature of the patient population;
- the patient eligibility criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to study sites;
- the design of the trial;
- · our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new products that may be approved for the indications we are investigating;
- our ability to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion.

In addition, our clinical trials may compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates or approved products for the same clinical indications, and this competition may reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors, or chose to be treated using Luxturna, a commercially available product by Spark Therapeutics, Inc. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which may reduce the number of patients who are available for our clinical trials in such clinical trial site.

Delays or failures in planned patient enrollment or retention may result in increased costs, program delays or both, which could have a harmful effect on our ability to develop our product candidates, or could render further development impossible.

Our product candidates may cause serious adverse events or undesirable side effects or have other properties which may delay or prevent their regulatory approval, limit the commercial profile of an approved label, or, result in significant negative consequences following marketing approval, if any.

Serious adverse events or undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA, EMA or other authorities. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects, toxicities or unexpected characteristics, including death. A risk in any gene therapy product based on viral vectors is the risk of insertional oncogenesis.

If unacceptable side effects or deaths arise in the development of our product candidates, we, the FDA, the IRBs at the institutions in which our studies are conducted, DSMB, EMA or CAT could suspend or terminate our clinical trials or the FDA, EMA or other regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. Undesirable side effects or deaths in clinical trials with our product candidates may cause the FDA or comparable foreign regulatory authorities to place a clinical hold on the associated clinical trials, to require additional studies, or otherwise to delay or deny approval of our product candidates for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We expect to have to train medical personnel using our product candidates to understand the side effect profiles for our clinical trials and upon any commercialization of any of our product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in patient injury or death. Any of these occurrences may harm our business, financial condition and prospects significantly.

If any of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by any such product, including during any long-term follow-up observation period recommended or required for patients who receive treatment using our products, a number of potentially significant negative consequences could result, including:

- · regulatory authorities may withdraw approvals of such product;
- we may be required to recall a product or change the way such product is administered to patients;
- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product;
- regulatory authorities may require additional warnings on the label, such as a "black box" warning or contraindication;
- we may be required to implement a Risk Evaluation and Mitigation Strategy, or REMS, or create a medication guide outlining the risks
  of such side effects for distribution to patients;
- the product could become less competitive;
- · we could be sued and held liable for harm caused to patients; and
- · our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations and prospects.

# Success in preclinical studies or clinical trials may not be indicative of results in future clinical trials.

Results from previous preclinical studies or clinical trials are not necessarily predictive of future clinical trial results, and interim results of a clinical trial are not necessarily indicative of final results. Our product candidates may fail to show the desired safety and efficacy in clinical development despite positive results in preclinical studies or having successfully advanced through initial clinical trials.

Success in preclinical testing and early clinical trials does not ensure that later clinical trials will generate the same results or otherwise provide adequate data to demonstrate the efficacy and safety of a product candidate. Frequently, product candidates that have shown promising results in early clinical trials have subsequently suffered significant setbacks in later clinical trials. In addition, the design of a clinical trial can

determine whether its results will support approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. We have limited experience designing clinical trials and may be unable to design and execute a clinical trial to support regulatory approval. There is a high failure rate for drugs and biologic products proceeding through clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in preclinical testing and earlier-stage clinical trials. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, we may experience regulatory delays or rejections as a result of many factors, including due to changes in regulatory policy during the period of our product candidate development. Any such delays could negatively impact our business, financial condition, results of operations and prospects.

The regulatory approval processes of the FDA, EMA and other regulatory authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

The time required to obtain approval by the FDA, EMA and other regulatory authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate and it is possible that none of our product candidates in clinical programs or any other product candidates we may seek to develop in the future will ever obtain regulatory approval. Neither we nor any future collaborator is permitted to market any of our product candidates in the United States or the European Union until we receive regulatory approval of a BLA from the FDA or a MAA from the EMA, respectively. It is possible that the FDA may refuse to accept for substantive review any biologic license applications, or BLAs, or the EMA any of our MAAs, that we submit for our product candidates or may conclude after review of our data that our application is insufficient to obtain marketing approval of our product candidates.

Prior to obtaining approval to commercialize a product candidate in the United States, the European Union or elsewhere, we or our collaborators must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA, EMA or foreign regulatory agencies, that such product candidates are safe and effective for their intended uses. Results from nonclinical studies and clinical trials can be interpreted in different ways. Even if we believe the nonclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA, EMA or other regulatory authorities. The FDA or EMA may also require us to conduct additional preclinical studies or clinical trials for our product candidates either prior to or post-approval, or it may object to elements of our clinical development program. Depending on the extent of these or any other FDA or EMA required studies, approval of any regulatory approval applications that we submit may be delayed by several years, or may require us to expend significantly more resources than we have available.

Of the large number of potential products in development, only a small percentage successfully complete the FDA, EMA or other foreign regulatory approval processes and are commercialized. The lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, results of operations and prospects.

Even if we obtain FDA or EMA approval for AAV-CNGB3, AAV-CNGA3, AAV-RPGR, AAV-RPE65 or AAV-AQP1 in the United States or European Union, we may never obtain approval for or commercialize it in any other jurisdiction, which would limit our ability to realize their full market potential.

In order to market any products in any particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a country-by-country basis regarding safety and efficacy.

Approval by the FDA in the United States or the EMA in the European Union does not ensure approval by regulatory authorities in other countries or jurisdictions. However, the failure to obtain approval in one jurisdiction may negatively impact our ability to obtain approval elsewhere. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country.

Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and increased costs for us and require additional preclinical studies or clinical trials which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. We do not have any product candidates approved for sale in any jurisdiction, including in international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of any product we develop will be unrealized.

Even if we receive regulatory approval of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

Any product candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, packaging, distribution, adverse event reporting, storage, recordkeeping, export, import, advertising and promotional activities for such product, among other things, will be subject to extensive and ongoing requirements of and review by the FDA, EMA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, establishment registration and drug listing requirements, continued compliance with cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping and GCP requirements for any clinical trials that we conduct post-approval.

The FDA and EMA closely regulate the post-approval marketing and promotion of genetic therapy medicines to ensure they are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA and EMA imposes stringent restrictions on manufacturers' communications regarding off-label use and if we market our products for uses beyond their approved indications, we may be subject to enforcement action for off-label marketing. Violations of the U.S. federal Food, Drug, and Cosmetic Act, or FDCA, relating to the promotion of prescription drugs may lead to FDA enforcement actions and investigations alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws.

In addition, later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on manufacturing such products;
- restrictions on the labeling or marketing of a product;
- · restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;

- warning letters or holds on clinical trials;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products;
- · product seizure or detention; or
- injunctions or the imposition of civil or criminal penalties.

The FDA's policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. For example, in December 2016, the 21st Century Cures Act, or Cures Act, was signed into law. The Cures Act, among other things, is intended to modernize the regulation of drugs and biologics and spur innovation and contains provisions applicable to the development of gene therapies, but its ultimate implementation is unclear. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained which would adversely affect our business, prospects and ability to achieve or sustain profitability.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the Trump administration may impact our business and industry. Namely, the Trump administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict how these requirements will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

Interim "top-line" and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim "top-line" or preliminary data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or "top-line" data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on research programs and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to timely capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

#### Risks Related to Healthcare Laws and Other Legal Compliance Matters

Enacted and future healthcare legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and may affect the prices we may set.

In the United States, the European Union and other jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers. Among the provisions of the ACA, those of greatest importance to the pharmaceutical and biotechnology industries include the following:

- an annual, non-deductible fee payable by any entity that manufactures or imports certain branded prescription drugs and biologic agents (other than those designated as orphan drugs), which is apportioned among these entities according to their market share in certain government healthcare programs;
- new requirements to report certain financial arrangements with physicians and teaching hospitals, including reporting "transfers of value" made or distributed to prescribers and other healthcare providers and reporting investment interests held by physicians and their immediate family members;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain
  individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate
  liability;
- a licensure framework for follow on biologic products;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and
- establishment of a Center for Medicare Innovation at the Centers for Medicare & Medicaid Services, or CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. Most recently, the Tax Cuts and Jobs Act of 2017 was enacted, which includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". The current Trump administration and Congress will likely continue to seek to modify, repeal, or otherwise invalidate all, or certain provisions of, the ACA. It is uncertain the extent to which any such changes may impact our business or financial condition.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, led to aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect in April 2013 and, due to subsequent legislative amendments to the statute will remain in effect through 2027 unless additional action is taken by Congress. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws or any other similar laws introduced in the future may result in additional reductions in Medicare and other health care funding, which could negatively affect our customers and accordingly, our financial operations.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as bundled payment models. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, and review the relationship between pricing and manufacturer patient programs. The Trump administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Additionally, on May 11, 2018, President Trump laid out his administration's "Blueprint" to reduce the cost of prescription drugs while preserving innovation and cures. The Department of Health and Human Services, or HHS, has already started the process of soliciting feedback on some of these measures and, at the same time, is immediately implementing others under its existing authority. Although some of these, and other, proposals will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand

Individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our product candidates or put pressure on our product pricing.

In the European Union, similar political, economic and regulatory developments may affect our ability to profitably commercialize our product candidates, if approved. In addition to continuing pressure on prices and cost containment measures, legislative developments at the EU or member state level may result in significant

additional requirements or obstacles that may increase our operating costs. The delivery of healthcare in the European Union, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than European Union, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most EU member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing European Union and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to commercialize our product candidates, if approved.

In markets outside of the United States and the European Union, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the United States, the European Union or any other jurisdiction. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

Our business operations and current and future relationships with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our product candidates, if approved. Such laws include:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or providing any remuneration (including any kickback, bribe, or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under U.S. federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the U.S. federal civil and criminal false claims and civil monetary penalties laws, including the civil False Claims Act, which prohibit, among other things, , including through civil whistleblower or qui tam actions, individuals or entities from knowingly presenting, or causing to be presented, to the U.S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- the U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal statutes which prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program,

or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and its implementing
  regulations, which imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy,
  security and transmission of individually identifiable health information without appropriate authorization by covered entities subject to
  the rule, such as certain health plans, healthcare clearinghouses and healthcare providers as well as their business associates,
  independent contractors of a covered entity that perform certain services involving the use or disclosure of individually identifiable
  health information;
- the FDCA, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;
- the U.S. Public Health Service Act, which prohibits, among other things, the introduction into interstate commerce of a biological product unless a biologics license is in effect for that product;
- the U.S. Physician Payments Sunshine Act and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report annually to the government information related to certain payments and other transfers of value to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;
- analogous U.S. state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; state and local laws that require the registration of pharmaceutical sales representatives; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; and
- similar healthcare laws and regulations in the European Union and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, such as Medicare and Medicaid or similar programs in other countries or jurisdictions, integrity oversight and reporting

obligations to resolve allegations of non-compliance, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment, which could affect our ability to operate our business. Further, defending against any such actions can be costly, time-consuming and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

We are subject to environmental, health and safety laws and regulations, and we may become exposed to liability and substantial expenses in connection with environmental compliance or remediation activities.

Our operations, including our development, testing and manufacturing activities, are subject to numerous environmental, health and safety laws and regulations. These laws and regulations govern, among other things, the controlled use, handling, release and disposal of and the maintenance of a registry for, hazardous materials and biological materials, such as chemical solvents, human cells, carcinogenic compounds, mutagenic compounds and compounds that have a toxic effect on reproduction, laboratory procedures and exposure to blood-borne pathogens. If we fail to comply with such laws and regulations, we could be subject to fines or other sanctions.

As with other companies engaged in activities similar to ours, we face a risk of environmental liability inherent in our current and historical activities, including liability relating to releases of or exposure to hazardous or biological materials. Environmental, health and safety laws and regulations are becoming more stringent. We may be required to incur substantial expenses in connection with future environmental compliance or remediation activities, in which case, the production efforts of our third-party manufacturers or our development efforts may be interrupted or delayed.

Due to our international operations, we are subject to anti-corruption laws, as well as export control laws, customs laws, sanctions laws and other laws governing our operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, other remedial measures and legal expenses.

Our operations are subject to anti-corruption laws, including the U.K. Bribery Act 2010, or Bribery Act; the U.S. Foreign Corrupt Practices Act, or FCPA; and other anti-corruption laws that apply in countries where we do business and may do business in the future. The Bribery Act, FCPA, and these other laws generally prohibit us, our officers and our employees and intermediaries from bribing, being bribed by, or providing prohibited payments or anything else of value to government officials or other persons to obtain or retain business or gain some other business advantage. We may in the future operate in jurisdictions that pose a high risk of potential Bribery Act or FCPA violations, and we may participate in collaborations and relationships with third parties whose actions could potentially subject us to liability under the Bribery Act, FCPA, or local anti-corruption laws. In addition, we cannot predict the nature, scope, or effect of future regulatory requirements to which any of our international operations might be subject or the manner in which existing laws might be administered or interpreted.

We also are subject to other laws and regulations governing any international operations, including regulations administered by the governments of the United Kingdom and the United States, and authorities in the EU, including applicable export control regulations, economic sanctions on countries and persons, customs requirements and currency exchange regulations, or, collectively, the Trade Control laws.

There is no assurance that we will be completely effective in ensuring our compliance with all applicable anti-corruption laws, including the Bribery Act, the FCPA, or other legal requirements, including Trade Control laws. If we are not in compliance with the Bribery Act, the FCPA, and other anti-corruption laws or Trade Control laws, we may be subject to criminal and civil penalties, disgorgement, and other sanctions and

remedial measures and legal expenses. Any investigation of any potential violations of the Bribery Act, the FCPA, other anti-corruption laws, or Trade Control laws by U.K., U.S., or other authorities, even if it is ultimately determined that we did not violate such laws, could be costly and time-consuming, require significant personnel resources, and harm our reputation.

We will seek to build and continuously improve our systems of internal controls and to remedy any weaknesses identified. There can be no assurance, however, that the policies and procedures will be followed at all times or effectively detect and prevent violations of the applicable laws by one or more of our employees, consultants, agents, or collaborators and, as a result, we could be subject to fines, penalties, or prosecution.

#### **Risks Related to Commercialization**

We face significant competition in an environment of rapid technological change, and there is a possibility that our competitors may achieve regulatory approval before us or develop therapies that are safer or more advanced or effective than ours, which may harm our financial condition and our ability to successfully market or commercialize any product candidates we may develop.

The development and commercialization of new gene therapy products is highly competitive. Moreover, the gene regulation and manufacturing fields are characterized by rapidly changing technologies, significant competition, and a strong emphasis on intellectual property. We will face competition with respect to any product candidates that we may seek to develop or commercialize in the future from major pharmaceutical companies, specialty pharmaceutical companies, and biotechnology companies worldwide. Potential competitors also include academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing, and commercialization.

There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of the disease indications for which we have research programs, including inherited retinal diseases and neurodegenerative diseases. Some of these competitive products and therapies are based on scientific approaches that are similar to our approach, and others are based on entirely different approaches.

Our platform and products focus on the development of gene therapies and gene regulation technology. There are a number of companies developing gene therapy products include Applied Genetic Technologies Corporation, Nightstar Therapeutics plc and Spark Therapeutics, Inc. In addition to competition from other gene therapies, any products we may develop may also face competition from other types of therapies, such as small molecule, antibody, protein or other therapies.

Many of our current or potential competitors, either alone or with their collaboration partners, have greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical, biotechnology, and gene therapy industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any products that we may develop or that would render any products that we may develop obsolete or non-competitive. Our competitors also may obtain FDA, EMA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able

to enter the market. Additionally, technologies developed by our competitors may render our potential product candidates uneconomic or obsolete, and we may not be successful in marketing any product candidates we may develop against competitors.

In addition, as a result of the expiration or successful challenge of our patent rights, we could face more litigation with respect to the validity and/or scope of patents relating to our competitors' products. The availability of our competitors' products could limit the demand, and the price we are able to charge, for any products that we may develop and commercialize.

The successful commercialization of our product candidates will depend in part on the extent to which governmental authorities and health insurers establish coverage, adequate reimbursement levels and pricing policies. Failure to obtain or maintain coverage and adequate reimbursement for our product candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue.

The availability of coverage and adequacy of reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payors are essential for most patients to be able to afford medical services and pharmaceutical products such as our product candidates, assuming FDA approval. Our ability to achieve acceptable levels of coverage and reimbursement for our products or procedures using our products by governmental authorities, private health insurers and other organizations will have an effect on our ability to successfully commercialize our product candidates. Obtaining coverage and adequate reimbursement for our products may be particularly difficult because of the higher prices often associated with drugs administered under the supervision of a physician. Separate reimbursement for the product itself or the treatment or procedure in which our product is used may not be available. A decision by a third-party payor not to cover or separately reimburse for our products or procedures using our products, could reduce physician utilization of our products once approved. Assuming there is coverage for our product candidates or procedures using our product candidates by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. We cannot be sure that coverage and reimbursement in the United States, the European Union or elsewhere will be available for our product candidates or any product that we may develop, and any reimbursement that may become available may not be adequate or may be decreased or eliminated in the future.

Third-party payors increasingly are challenging prices charged for pharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs or biologics when an equivalent generic drug, biosimilar or a less expensive therapy is available. It is possible that a third-party payor may consider our product candidates as substitutable and only offer to reimburse patients for the less expensive product. Even if we show improved efficacy or improved convenience of administration with our product candidates, pricing of existing third-party therapeutics may limit the amount we will be able to charge for our product candidates. These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in our product candidates. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our product candidates, and may not be able to obtain a satisfactory financial return on our product candidates.

There is significant uncertainty related to the insurance coverage and reimbursement of newly-approved products. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs and biologics will be covered. The Medicare and Medicaid programs increasingly are used as models in the United States for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs and biologics. Some third-party payors may require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who use such therapies. We cannot predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates.

No uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases on short notice, and we believe that changes in these rules and regulations are likely.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe and other countries have and will continue to put pressure on the pricing and usage of our product candidates. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our product candidates may be reduced compared with the United States and may be insufficient to generate commercially-reasonable revenue and profits.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. We expect to experience pricing pressures in connection with the sale of our product candidates due to the trend toward managed health care, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and biologics and surgical procedures and other treatments, has become intense. As a result, increasingly high barriers are being erected to the entry of new products.

Even if our product candidates receive marketing approval, they may fail to achieve market acceptance by physicians, patients, third-party payors or others in the medical community necessary for commercial success.

If our product candidates receive marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. If they do not achieve an adequate level of acceptance, we may not generate significant product revenues or become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including but not limited to:

- the efficacy and potential advantages compared to alternative treatments;
- effectiveness of sales and marketing efforts;
- the cost of treatment in relation to alternative treatments, including any similar generic treatments;
- our ability to offer our products for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support;
- the timing of market introduction of competitive products;

- the availability of third-party coverage and adequate reimbursement;
- product labeling or product insert requirements of the FDA, EMA or other regulatory authorities, including any limitations or warnings contained in a product's approved labeling;
- · the prevalence and severity of any side effects; and
- · any restrictions on the use of our product together with other medications.

Because we expect sales of our product candidates, if approved, to generate substantially all of our product revenues for a substantial period, the failure of this product to find market acceptance would harm our business and could require us to seek additional financing.

If we are unable to establish sales, marketing and distribution capabilities either on our own or in collaboration with third parties, we may not be successful in commercializing our product candidates or realizing the synergies in the target indications of our programs, even if they are approved.

We do not have any infrastructure for the sales, marketing or distribution of our products, and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. We expect to build a focused sales, distribution and marketing infrastructure to market our product candidates in the United States and European Union, if approved. There are significant expenses and risks involved with establishing our own sales, marketing and distribution capabilities, including our ability to hire, retain and appropriately incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities could delay any product launch, which would adversely impact the commercialization of our product candidates. Additionally, if the commercial launch of our product candidates for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

We may not have the resources in the foreseeable future to allocate to the sales and marketing of our product candidates in certain international markets. Therefore, our future sales in these markets will largely depend on our ability to enter into and maintain collaborative relationships for such capabilities, the collaborator's strategic interest in the product and such collaborator's ability to successfully market and sell the product. We may pursue collaborative arrangements regarding the sale and marketing of AAV-CNGB3, AAV-CNGA3, AAV-RPGR, AAV-RPE65 and AAV-AQP1, if approved, for certain markets overseas; however, we cannot assure that we will be able to establish or maintain such collaborative arrangements, or if able to do so, that they will have effective sales forces.

If we are unable to build our own sales force or negotiate a collaborative relationship for the commercialization of AAV-CNGB3, AAV-CNGA3, AAV-RPGR, AAV-RPE65 and AAV-AQP1, we may be forced to delay the potential commercialization of AAV-CNGB3, AAV-CNGA3, AAV-RPGR, AAV-RPE65 and AAV-AQP1 or reduce the scope of our sales or marketing activities for AAV-CNGB3, AAV-CNGA3, AAV-RPGR, AAV-RPE65 and AAV-AQP1. If we elect to increase our expenditures to fund commercialization activities internationally, we will need to obtain additional capital, which may not be available to us on acceptable terms, or at all. We could enter into arrangements with collaborative partners at an earlier stage than otherwise would be ideal and we may be required to relinquish rights to AAV-CNGB3, AAV-CNGA3, AAV-RPGR, AAV-RPE65 and AAV-AQP1 or otherwise agree to terms unfavorable to us, any of which may have an adverse effect on our business, operating results and prospects.

Some indications targeted by our ophthalmology programs are rare, but we anticipate realizing synergies in commercializing of our IRD product candidates, should they be approved. Failure to realize synergies in our sales, marketing and distribution efforts may harm our commercialization efforts.

If we are unable to establish adequate sales, marketing and distribution capabilities, either on our own or in collaboration with third parties, we will not be successful in commercializing AAV-CNGB3, AAV-CNGA3, AAV-RPGR, AAV-RPE65 and AAV-AQP1 and may not become profitable and may incur significant additional losses. We will be competing with many companies that currently have extensive and well-funded marketing and sales operations. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

If we obtain approval to commercialize any products outside of the United States or the European Union, a variety of risks associated with international operations could adversely affect our business.

If AAV-CNGB3, AAV-CNGA3, AAV-RPGR, AAV-RPE65 and AAV-AQP1 are approved for commercialization, we intend to enter into agreements with third parties to market them in certain jurisdictions outside the United States and the European Union. We expect that we will be subject to additional risks related to international pharmaceutical operations, including:

- different regulatory requirements for drug and biologic approvals and rules governing drug and biologic commercialization in foreign countries;
- reduced protection for intellectual property rights;
- foreign reimbursement, pricing and insurance regimes;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- · economic weakness, including inflation, or political instability in particular foreign economies and markets;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- business interruptions resulting from geopolitical actions, including war and terrorism or natural disasters including earthquakes, typhoons, floods and fires, or from economic or political instability;
- greater difficulty with enforcing our contracts;
- potential noncompliance with the U.S. Foreign Corrupt Practices Act, the U.K. Bribery Act 2010 and similar anti-bribery and anticorruption laws in other jurisdictions; and
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad.

We have no prior experience in these areas. In addition, there are complex regulatory, tax, labor and other legal requirements imposed by individual countries in Europe with which we will need to comply. If we are unable to successfully manage the challenges of international expansion and operations, our business and operating results could be harmed.

Any product candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated.

The ACA includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or

interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own pre-clinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement BPCIA may be fully adopted by the FDA, any such processes could have an adverse effect on the future commercial prospects for our biological products.

There is a risk that any of our product candidates approved as a biological product under a BLA would not qualify for the 12-year period of exclusivity or that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

#### Risks Related to Our Dependence on Third Parties

If our recently completed cGMP manufacturing facility is unable to supply our product candidates for all of our current preclinical, clinical and potential commercial needs, we will be forced to seek out third-party manufacturers. We currently contract with third parties for the manufacture of plasmid used in producing our product candidates. Relying on third parties increases the risk that we will not have sufficient quantities of such materials, product candidates, or any medicines that we may develop and commercialize, or that such supply will not be available to us at an acceptable cost, which could delay, prevent, or impair our development or commercialization efforts.

We have begun producing our product candidates in our facility. However, if our facility is damaged, suffers any form of delay or regulatory challenges, or we are unable to scale our internal manufacturing capabilities to meet demand for our product candidates, we will need to contract with third-party manufacturers to produce our product candidates.

We currently rely on third-party manufacturers for the manufacture of plasmid used in the production of our product candidates. We do not have a long term supply agreement with any of the third-party manufacturers, and we purchase our required supply on a purchase order basis.

We may be unable to establish any agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- the possible breach of the manufacturing agreement by the third party;
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us; and
- · reliance on the third party for regulatory compliance, quality assurance, safety, and pharmacovigilance and related reporting.

Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements that might be required by the FDA or EMA. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocations, seizures or recalls of product candidates or medicines, operating restrictions, and criminal prosecutions, any of which could adversely affect supplies of our candidates and harm our business, financial condition, results of operations, and prospects.

Any therapies that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us. Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval.

Our current and anticipated future dependence upon others for the manufacture of any product candidates we may develop or any components required for the manufacture of our product candidates may adversely affect our future profit margins and our ability to commercialize any product candidates that receive marketing approval on a timely and competitive basis.

We may collaborate with third parties for the development and commercialization of our product candidates. We may not succeed in establishing and maintaining collaborative relationships, which may significantly limit our ability to develop and commercialize our product candidates successfully, if at all.

We may seek collaborative relationships for the development and commercialization of our product candidates. Failure to obtain a collaborative relationship for our product candidates may significantly impair their commercial potential. We also may need to enter into collaborative relationships to provide funding to support our other research and development programs. The process of establishing and maintaining collaborative relationships is difficult, time-consuming and involves significant uncertainty, such as:

- a collaboration partner may shift its priorities and resources away from our product candidates due to a change in business strategies, or a merger, acquisition, sale or downsizing;
- a collaboration partner may seek to renegotiate or terminate their relationships with us due to unsatisfactory clinical results, manufacturing issues, a change in business strategy, a change of control or other reasons;
- a collaboration partner may cease development in therapeutic areas which are the subject of our strategic collaboration;
- · a collaboration partner may not devote sufficient capital or resources towards our product candidates;
- a collaboration partner may change the success criteria for a product candidate thereby delaying or ceasing development of such candidate;
- a significant delay in initiation of certain development activities by a collaboration partner will also delay payment of milestones tied to such activities, thereby impacting our ability to fund our own activities;
- a collaboration partner could develop a product that competes, either directly or indirectly, with our product candidate;
- a collaboration partner with commercialization obligations may not commit sufficient financial or human resources to the marketing, distribution or sale of a product;

- a collaboration partner with manufacturing responsibilities may encounter regulatory, resource or quality issues and be unable to meet demand requirements;
- a collaboration partner may terminate a strategic alliance;
- a dispute may arise between us and a partner concerning the research, development or commercialization of a product candidate
  resulting in a delay in milestones, royalty payments or termination of an alliance and possibly resulting in costly litigation or arbitration
  which may divert management attention and resources; and
- · a partner may use our products or technology in such a way as to make us subject to litigation with a third party.

If any collaborator fails to fulfill its responsibilities in a timely manner, or at all, our research, clinical development, manufacturing or commercialization efforts related to that collaboration could be delayed or terminated, or it may be necessary for us to assume responsibility for expenses or activities that would otherwise have been the responsibility of our collaborator. If we are unable to establish and maintain collaborative relationships on acceptable terms or to successfully transition terminated collaborative agreements, we may have to delay or discontinue further development of one or more of our product candidates, undertake development and commercialization activities at our own expense or find alternative sources of capital. Moreover, any collaborative partners we enter into agreements with in the future may shift their priorities and resources away from our product candidates or seek to renegotiate or terminate their relationships with us.

#### **Risks Related to Intellectual Property**

We depend on proprietary technology licensed from others. If we lose our existing licenses or are unable to acquire or license additional proprietary rights from third parties, we may not be able to continue developing our product candidates.

We currently in-license certain intellectual property from UCL Business, Plc, or UCLB, and Brandeis University, or Brandeis. We are a party to agreements with UCL for certain technology and AAV vector-related patents and with Brandeis for certain preclinical technology for the treatment of ALS, and we may enter into additional agreements, including license agreements, with other parties in the future that impose diligence, development and commercialization timelines, milestone payments, royalties, insurance and other obligations on us. For example, in exchange for the rights granted to us by UCL, we are obligated to pay an annual management fee, milestone payments for certain commercial sales thresholds, and a certain percentages of proceeds on sublicensing revenues. If we fail to comply with our obligations to UCL, Brandeis, or any of our other collaborators, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market any product candidate that is covered by these agreements, which could adversely affect the value of the product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms, or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology.

We may rely on other third parties from whom we license proprietary technology to file and prosecute patent applications and maintain patents and otherwise protect the intellectual property we license from them. We may have limited control over these activities or any other intellectual property that may be related to our in-licensed intellectual property. For example, we cannot be certain that such activities by these licensors will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. We may have limited control over the manner in which our licensors initiate an infringement proceeding against a third-party infringer of the intellectual property rights, or defend certain of the intellectual property that may be licensed to us. It is possible that the licensors' infringement proceeding or

defense activities may be less vigorous than if we conduct them ourselves. The licensing and acquisition of third-party intellectual property rights is a competitive practice, and companies that may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their larger size and cash resources or greater clinical development and commercialization capabilities. There can be no assurance that we will be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to acquire. Furthermore, we may be unable to in-license any compositions, methods of use, processes, or other third-party intellectual property rights from third parties, which we identify as necessary for our product candidates.

If we are unable to obtain and maintain patent protection for our technology and product candidates or if the scope of the patent protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our proprietary technologies, product candidate development programs and product candidates. Our success depends in large part on our ability to secure and maintain patent protection in the United States and other countries with respect to our current product candidates and any future product candidates we may develop. We seek to protect our proprietary position by filing or collaborating with our licensors to file patent applications in the United States and abroad related to our proprietary technologies, development programs and product candidates. The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. Moreover, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain.

It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. We may not have the right to control the preparation, filing, and prosecution of patent applications, or to maintain the rights to patents licensed to third parties. Therefore, these patents and patent applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our proprietary products and technology, including current product candidates, any future product candidates we may develop, and our gene regulation technology in the United States or in other foreign countries, in whole or in part. Alternately, our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from using our technology or from developing competing products and technologies. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found, which can prevent a patent from issuing from a pending patent application or later invalidate or narrow the scope of an issued patent. For example, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or, in some cases, not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. Even if patents do successfully issue and even if such patents cover our current product candidates, any future product candidates we may develop and our gene regulation technology, third parties may challenge their validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated, or held unenforceable. Any successful challenge to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any of our product candidates or gene regulation technology. Our competitors may be able to circumvent our patents by developing similar or alternative product candidates in a non-infringing manner. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate and our gene regulation technology under patent protection could be reduced.

If the patent applications we hold or have in-licensed with respect to our development programs and product candidates fail to issue, if their validity, breadth or strength of protection is threatened, or if they fail to

provide meaningful exclusivity for any of our current or future product candidates or technology, it could dissuade companies from collaborating with us to develop product candidates, encourage competitors to develop competing products or technologies and threaten our ability to commercialize future product candidates. Any such outcome could harm our business.

The patent position of biotechnology and pharmaceutical companies is highly uncertain, involves complex legal and factual questions, and is characterized by the existence of large numbers of patents and frequent litigation based on allegations of patent or other intellectual property infringement or violation. In addition, the laws of jurisdictions outside the United States may not protect our rights to the same extent as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States law does. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. Since patent applications in the United States and other jurisdictions are confidential for a period of time after filing, we cannot be certain that we were the first to file for patents covering our inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in the issuance of patents, or may result in the issuance of patents which fail to protect our technology or products, in whole or in part, or which fail to effectively prevent others from commercializing competitive technologies and products.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Thus, even if our patent applications issue as patents, they may not issue in a form that will provide us with meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Moreover, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however the life of a patent, and the protection it affords, is limited. Without patent protection for our current or future product candidates, we may be open to competition from generic versions of such products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Third parties may assert claims against us alleging infringement of their patents and proprietary rights, or we may need to become involved in lawsuits to defend or enforce our patents, either of which could result in substantial costs or loss of productivity, delay or prevent the development and commercialization of our product candidates, prohibit our use of proprietary technology or sale of products or put our patents and other proprietary rights at risk.

Our commercial success depends, in part, upon our ability to develop, manufacture, market and sell our product candidates without alleged or actual infringement, misappropriation or other violation of the patents and proprietary rights of third parties. However, our research, development and commercialization activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. Litigation relating to infringement or misappropriation of patent and other intellectual property rights in the pharmaceutical and biotechnology industries is common, including patent infringement lawsuits, interferences, oppositions and *inter partes* reviews, and reexamination proceedings before the U.S. Patent and Trademark Office, or USPTO, and corresponding foreign patent offices. The various markets in which we plan to operate are subject to frequent and extensive litigation regarding patents and other intellectual property rights. In addition, many companies in intellectual property-dependent industries, including the biotechnology and pharmaceutical industries, have employed intellectual property litigation as a means to gain an

advantage over their competitors. Numerous U.S., EU and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates, and as the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the intellectual property rights of third parties. Some claimants may have substantially greater resources than we do and may be able to sustain the costs of complex intellectual property litigation to a greater degree and for longer periods of time than we could. In addition, patent holding companies that focus solely on extracting royalties and settlements by enforcing patent rights may target us.

We may be subject to third-party claims including infringement, interference or derivation proceedings, post-grant review and inter partes review before the USPTO or similar adversarial proceedings or litigation in other jurisdictions. Even if such claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, and the holders of any such patents may be able to block our ability to commercialize the applicable product candidate unless we obtained a license under the applicable patents, or until such patents expire or are finally determined to be invalid or unenforceable. There may be third-party patents or patent applications with claims to compositions, formulations, or methods of treatment, prevention use, or manufacture of our product candidates or technologies. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover aspects of our compositions, formulations, or methods of treatment, prevention or use, the holders of any such patents may be able to prohibit our use of those compositions, formulations, methods of treatment, prevention or use or other technologies, effectively blocking our ability to develop and commercialize the applicable product candidate until such patent expires or is finally determined to be invalid or unenforceable or unless we obtained a license.

In addition, defending such claims would cause us to incur substantial expenses and, if successful, could cause us to pay substantial damages if we are found to be infringing a third party's patent rights. These damages potentially include increased damages (possibly treble damages) and attorneys' fees if we are found to have infringed such rights willfully. Further, if a patent infringement suit is brought against us or our third-party service providers, our development, manufacturing or sales activities relating to the product or product candidate that is the subject of the suit may be delayed or terminated. As a result of patent infringement claims, or in order to avoid potential infringement claims, we may choose to seek, or be required to seek, a license from the third party, which may require payment of substantial royalties or fees, or require us to grant a cross-license under our intellectual property rights. These licenses may not be available on reasonable terms or at all. Even if a license can be obtained on reasonable terms, the rights may be nonexclusive, which would give our competitors access to the same intellectual property rights. If we are unable to enter into a license on acceptable terms, we could be prevented from commercializing one or more of our product candidates, or forced to modify such product candidates, or to cease some aspect of our business operations, which could harm our business significantly. We might also be forced to redesign or modify our product candidates so that we no longer infringe the third-party intellectual property rights, which may result in significant cost or delay to us, or which redesign or modification could be impossible or technically infeasible. Even if we were ultimately to prevail, any of these events could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business. In addition, if the breadth or strength of protection provided the patents and patent applications we own or in-license is

Competitors may infringe our patents or other intellectual property. If we or one of our licensors were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that our patent is invalid or unenforceable. In patent litigation in the United States and in Europe, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of

novelty, obviousness lack of written description, or non-enablement. Third parties might allege unenforceability of our patents because during prosecution of the patent an individual connected with such prosecution withheld relevant information, or made a misleading statement. Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications. The outcome of proceedings involving assertions of invalidity and unenforceability during patent litigation is unpredictable. With respect to the validity of patents, for example, we cannot be certain that there is no invalidating prior art of which we and the patent examiner were unaware during prosecution, but that an adverse third party may identify and submit in support of such assertions of invalidity. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Our patents and other intellectual property rights also will not protect our technology if competitors design around our protected technology without infringing our patents or other intellectual property rights.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors view these announcements in a negative light, the price of our ordinary shares could be adversely affected. Such litigation or proceedings could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have an adverse effect on our ability to compete in the marketplace.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might adversely affect our ability to develop, manufacture and market our product candidates.

We cannot guarantee that any of our or our licensors' patent searches or analyses, including but not limited to the identification of relevant patents, analysis of the scope of relevant patent claims or determination of the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States, Europe and elsewhere that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction. For example, in the United States, applications filed before November 29, 2000 and certain applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Patent applications in the United States, the European Union and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our product candidates could be filed by others without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our product candidates or the use of our product candidates. After issuance, the scope of patent claims remains subject to construction as determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our product candidates. We may incorrectly determine that our product candidates are not covered by a third-party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States, the European Union or elsewhere that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our product candidates. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our product candidates.

If we fail to correctly identify or interpret relevant patents, we may be subject to infringement claims. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay monetary damages, we may be temporarily or permanently prohibited from commercializing our product candidates. We might, if possible, also be forced to redesign our product candidates in a manner that no longer infringes third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

Changes in patent laws or patent jurisprudence could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biotechnology companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biotechnology and genetic medicine industries involve both technological complexity and legal complexity. Therefore, obtaining and enforcing biotechnology and genetic medicine patents is costly, time-consuming and inherently uncertain. In addition, the Leahy-Smith America Invents Act, or the AIA, which was passed in September 2011, resulted in significant changes to the U.S. patent system.

An important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned from a "first-to-invent" to a "first-to-file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. Under a "first-to-file" system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to a patent on the invention regardless of whether another inventor had made the invention earlier. A third party that files a patent application in the USPTO after that date but before us could therefore be awarded a patent covering an invention of ours even if we made the invention before it was made by the third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application and diligent in filing patent applications, but circumstances could prevent us from promptly filing patent applications on our inventions.

Among some of the other changes introduced by the AIA are changes that limit where a patentee may file a patent infringement suit and providing opportunities for third parties to challenge any issued patent in the USPTO. This applies to all of our U.S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action.

Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. It is not clear what, if any, impact the AIA will have on the operation of our business. However, the AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our or our licensors' patent applications and the enforcement or defense of our or our licensors' issued patents.

We may become involved in opposition, interference, derivation, inter partes review or other proceedings challenging our or our licensors' patent rights, and the outcome of any proceedings are highly uncertain. An adverse determination in any such proceeding could reduce the scope of, or invalidate, our owned or in-licensed patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights.

Additionally, the U.S. Supreme Court has ruled on several patent cases in recent years either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in

certain situations, and there are other open questions under patent law that courts have yet to decisively address. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways and could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. In addition, the European patent system is relatively stringent in the type of amendments that are allowed during prosecution, but, the complexity and uncertainty of European patent laws has also increased in recent years. Complying with these laws and regulations could limit our ability to obtain new patents in the future that may be important for our business.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The USPTO, European and other patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO, European and other patent agencies over the lifetime of a patent. While an inadvertent failure to make payment of such fees or to comply with such provisions can in many cases be cured by additional payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance with such provisions will result in the abandonment or lapse of the patent or patent application, and the partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents within prescribed time limits. If we or our licensors fail to maintain the patents and patent applications covering our product candidates or if we or our licensors otherwise allow our patents or patent applications to be abandoned or lapse, it can create opportunities for competitors to enter the market, which would hurt our competitive position and could impair our ability to successfully commercialize our product candidates in any indication for which they are approved.

We enjoy only limited geographical protection with respect to certain patents and we may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents covering our product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In-licensing patents covering our product candidates in all countries throughout the world may similarly be prohibitively expensive, if such opportunities are available at all. And in-licensing or filing, prosecuting and defending patents even in only those jurisdictions in which we develop or commercialize our product candidates may be prohibitively expensive or impractical. Competitors may use our and our licensors' technologies in jurisdictions where we have not obtained patent protection or licensed patents to develop their own products and, further, may export otherwise infringing products to territories where we and our licensors have patent protection, but enforcement is not as strong as that in the United States or the European Union. These products may compete with our product candidates, and our or our licensors' patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

In addition, we may decide to abandon national and regional patent applications while they are still pending. The grant proceeding of each national or regional patent is an independent proceeding which may lead to situations in which applications may be rejected by the relevant patent office, while substantively similar applications are granted by others. For example, relative to other countries, China has a heightened requirement for patentability and specifically requires a detailed description of medical uses of a claimed drug. Furthermore, generic drug manufacturers or other competitors may challenge the scope, validity or enforceability of our or our licensors' patents, requiring us or our licensors to engage in complex, lengthy and costly litigation or other

proceedings. Generic drug manufacturers may develop, seek approval for and launch generic versions of our products. It is also quite common that depending on the country, the scope of patent protection may vary for the same product candidate or technology.

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws or regulations in the United States and the European Union, and many companies have encountered significant difficulties in protecting and defending proprietary rights in such jurisdictions. Moreover, the legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets or other forms of intellectual property, which could make it difficult for us to prevent competitors in some jurisdictions from marketing competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, are likely to result in substantial costs and divert our efforts and attention from other aspects of our business, and additionally could put at risk our or our licensors' patents of being invalidated or interpreted narrowly, could increase the risk of our or our licensors' patent applications not issuing, or could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, while damages or other remedies may be awarded to the adverse party, which may be commercially significant. If we prevail, damages or other remedies awarded to us, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Furthermore, while we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our product candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize our product candidates in all of our expected significant foreign markets. If we or our licensors encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished and we may face additional competition in those jurisdictions.

In some jurisdictions, compulsory licensing laws compel patent owners to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors are forced to grant a license to third parties under patents relevant to our business, or if we or our licensors are prevented from enforcing patent rights against third parties, our competitive position may be substantially impaired in such jurisdictions.

## Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

The term of any individual patent depends on applicable law in the country where the patent is granted. In the United States, provided all maintenance fees are timely paid, a patent generally has a term of 20 years from its application filing date or earliest claimed non-provisional filing date. Extensions may be available under certain circumstances, but the life of a patent and, correspondingly, the protection it affords is limited. Even if we or our licensors obtain patents covering our product candidates, when the terms of all patents covering a product expire, our business may become subject to competition from competitive medications, including generic medications. Given the amount of time required for the development, testing and regulatory review and approval of new product candidates, patents protecting such candidates may expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If we do not obtain patent term extension in the United States under the Hatch-Waxman Act and in foreign countries under similar legislation, thereby potentially extending the term of marketing exclusivity for our product candidates, our business may be harmed.

In the United States, a patent that covers an FDA-approved drug or biologic may be eligible for a term extension designed to restore the period of the patent term that is lost during the premarket regulatory review process conducted by the FDA. Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, which permits a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. In the European Union, our product candidates may be eligible for term extensions based on similar legislation. In either jurisdiction, however, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Even if we are granted such extension, the duration of such extension may be less than our request. If we are unable to obtain a patent term extension, or if the term of any such extension is less than our request, the period during which we can enforce our patent rights for that product will be in effect shortened and our competitors may obtain approval to market competing products sooner. The resulting reduction of years of revenue from applicable products could be substantial.

Our proprietary rights may not adequately protect our technologies and product candidates, and do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- others may be able to make products that are the same as or similar to our product candidates but that are not covered by the claims of
  the patents that we own or have exclusively licensed;
- others, including inventors or developers of our owned or in-licensed patented technologies who may become involved with
  competitors, may independently develop similar technologies that function as alternatives or replacements for any of our technologies
  without infringing our intellectual property rights;
- we or our licensors or our other collaboration partners might not have been the first to conceive and reduce to practice the inventions covered by the patents or patent applications that we own, license or will own or license;
- we or our licensors or our other collaboration partners might not have been the first to file patent applications covering certain of the patents or patent applications that we or they own or have obtained a license, or will own or will have obtained a license;
- we or our licensors may fail to meet obligations to the U.S. government with respect to in-licensed patents and patent applications funded by U.S. government grants, leading to the loss of patent rights;
- it is possible that our pending patent applications will not result in issued patents;
- it is possible that there are prior public disclosures that could invalidate our or our licensors' patents;

- issued patents that we own or exclusively license may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights, or in countries
  where research and development safe harbor laws exist, and then use the information learned from such activities to develop
  competitive products for sale in our major commercial markets;
- · ownership, validity or enforceability of our or our licensors' patents or patent applications may be challenged by third parties; and
- the patents of third parties or pending or future applications of third parties, if issued, may have an adverse effect on our business.

Our reliance on third parties may require us to share our trade secrets, which increases the possibility that our trade secrets will be misappropriated or disclosed, and confidentiality agreements with employees and third parties may not adequately prevent disclosure of trade secrets and protect other proprietary information.

We consider proprietary trade secrets, confidential know-how and unpatented know-how to be important to our business. We may rely on trade secrets and confidential know-how to protect our technology, especially where patent protection is believed by us to be of limited value. However, trade secrets and confidential know-how are difficult to protect, and we have limited control over the protection of trade secrets and confidential know-how used by our licensors, collaborators and suppliers. Because we have relied in the past on third parties to manufacture our product candidates, because we may continue to do so in the future, and because we expect to collaborate with third parties on the development of our current product candidates and any future product candidates we develop, we may, at times, share trade secrets with them. We also conduct joint research and development programs that may require us to share trade secrets under the terms of our research and development partnerships or similar agreements. Under such circumstances, trade secrets and confidential know-how can be difficult to maintain as confidential.

To protect this type of information against disclosure or appropriation by competitors, our policy is to require our employees, consultants, contractors and advisors to enter into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with us prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. However, current or former employees, consultants, contractors and advisers may unintentionally or willfully disclose our confidential information to competitors, and confidentiality agreements may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. The need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our competitive position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have an adverse effect on our business and results of operations. Enforcing a claim that a third party obtained illegally and is using trade secrets and/or confidential know-how is expensive, time consuming and unpredictable, and the enforceability of confidentiality agreements may vary from jurisdiction to jurisdiction. Courts outside the United States are sometimes less willing to protect proprietary information, technology and know-how.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. Despite our efforts to protect our trade secrets, our competitors may

discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third-party collaborators. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected. Our trademark MeiraGTx has been registered in the EU and a U.S. application is pending. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks or trademarks that incorporate variations of our unregistered trademarks or trade names. Over the long term, if we are unable to successfully register our trademarks and trade names and establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely impact our financial condition or results of operations.

We may need to license additional intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.

The growth of our business may depend in part on our ability to acquire or in-license additional proprietary rights. For example, our programs may involve product candidates that may require the use of additional proprietary rights held by third parties. Our product candidates may also require specific formulations to work effectively and efficiently. These formulations may be covered by intellectual property rights held by others. We may develop products containing our compositions and pre-existing pharmaceutical compositions. These pharmaceutical products may be covered by intellectual property rights held by others. We may be required by the FDA, EMA or other foreign regulatory authorities to provide a companion diagnostic test or tests with our product candidates. These diagnostic test or tests may be covered by intellectual property rights held by others. We may be unable to acquire or in-license any relevant third-party intellectual property rights that we identify as necessary or important to our business operations. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all, which would harm our business. We may need to cease use of the compositions or methods covered by such third-party intellectual property rights, and may need to seek to develop alternative approaches that do not infringe on such intellectual property rights which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license under such intellectual property rights, any such license may be non-exclusive, which may allow our competitors access to the same technologies licensed to us.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of their former employers or other third parties.

We employ individuals who were previously employed at other biotechnology or pharmaceutical companies. Although we seek to protect our ownership of intellectual property rights by ensuring that our agreements with our employees, collaborators and other third parties with whom we do business include provisions requiring such parties to assign rights in inventions to us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our patents. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we fail in

defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Even if we are successful, litigation could result in substantial cost and reputational loss and be a distraction to our management and other employees.

#### Risks Related to Employee Matters and Managing Growth

We will need to expand our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.

As of March 31, 2018, we had 59 full-time employees. We will need to significantly expand our organization, and we may have difficulty identifying, hiring and integrating new personnel. Future growth would impose significant additional responsibilities on our management, including the need to identify, recruit, maintain, motivate and integrate additional employees, consultants and contractors. Also, our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow revenues could be reduced, and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. If our management is unable to effectively manage our expected growth, our expenses may increase more than expected, our potential ability to generate revenue could be reduced and we may not be able to implement our business strategy. Many of the biotechnology companies that we compete against for qualified personnel and consultants have greater financial and other resources, different risk profiles and a longer history in the industry than we do. If we are unable to continue to attract and retain high-quality personnel and consultants, the rate and success at which we can discover and develop product candidates and operate our business will be limited.

## Our future success depends on our ability to retain our key personnel and to attract, retain and motivate qualified personnel.

Our industry has experienced a high rate of turnover of management personnel in recent years. We are highly dependent on the development, regulatory, commercialization and business development expertise of Alexandria Forbes, Ph.D., our President and Chief Executive Officer, Rich Giroux, our Chief Operating Officer and Stuart Naylor, Ph.D., our Chief Development Officer, as well as the other principal members of our management, scientific and clinical teams. Although we have formal employment agreements with our executive officers, these agreements do not prevent them from terminating their employment with us at any time and, for certain of our executive officers, entitle them to receive severance payments in connection with their voluntary resignation of employment. Additional details regarding these arrangements can be found in the section "Executive Compensation —Executive Compensation Arrangements."

If we lose one or more of our executive officers or key employees, our ability to implement our business strategy successfully could be seriously harmed. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain regulatory approval of and commercialize product candidates successfully. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these additional key personnel on acceptable terms given the

competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be engaged by entities other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to develop and commercialize product candidates will be limited.

## We expect to grow our organization, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of product candidate development, regulatory affairs and sales, marketing and distribution. Our management may need to divert a disproportionate amount of its attention away from our day-to-day activities to devote time to managing these growth activities. To manage these growth activities, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. Our inability to effectively manage the expansion of our operations may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees.

# Potential product liability lawsuits against us could cause us to incur substantial liabilities and limit commercialization of any products that we may develop.

The use of our product candidates in clinical trials and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by consumers, health care providers, pharmaceutical companies or others selling or otherwise coming into contact with our products. On occasion, large judgments have been awarded in class action lawsuits based on products that had unanticipated adverse effects. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation and significant negative media attention;
- withdrawal of participants from our clinical trials;
- significant costs to defend the related litigation and related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- inability to commercialize our product candidates;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- decreased demand for our product candidates, if approved for commercial sale; and
- · loss of revenue.

Our insurance policies are expensive and protect us only from some business risks, which leaves us exposed to significant uninsured liabilities.

We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include general liability, clinical trial liability, employment practices liability, property, auto, workers' compensation, umbrella, and directors' and officers' insurance.

Any additional product liability insurance coverage we acquire in the future, may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and in the future we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If we obtain marketing approval for our product candidates, we intend to acquire insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. A successful product liability claim or series of claims brought against us could cause our share price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business, including preventing or limiting the commercialization of any product candidates we develop. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended.

We also expect that operating as a public company will make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified people to serve on our board of directors, our board committees or as executive officers. We do not know, however, if we will be able to maintain existing insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our cash position and results of operations.

Our employees and independent contractors, including consultants, vendors, and any third parties we may engage in connection with development and commercialization may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could harm our business.

Misconduct by our employees and independent contractors, including consultants, vendors, and any third parties we may engage in connection with development and commercialization, could include intentional, reckless or negligent conduct or unauthorized activities that violate: (i) the laws and regulations of the FDA, EMA and other similar regulatory authorities, including those laws that require the reporting of true, complete and accurate information to such authorities; (ii) manufacturing standards; (iii) data privacy, security, fraud and abuse and other healthcare laws and regulations; or (iv) laws that require the reporting of true, complete and accurate financial information and data. Specifically, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws could also involve the improper use or misrepresentation of information obtained in the course of clinical trials, creation of fraudulent data in preclinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. Additionally, we are subject

to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid, other U.S. federal healthcare programs or healthcare programs in other jurisdictions, integrity oversight and reporting obligations to resolve allegations of non-compliance, individual imprisonment, other sanctions, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations.

## Our business and operations would suffer in the event of system failures.

Our computer systems, as well as those of our contractors and consultants, are vulnerable to damage from computer viruses, unauthorized access, natural disasters (including hurricanes), terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product candidate development programs. For example, the loss of preclinical study or clinical trial data from completed, ongoing or planned trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability and the further development of our product candidates could be delayed.

In the ordinary course of our business, we collect and store sensitive data, including intellectual property, clinical trial data, proprietary business information, personal data and personally identifiable information of our clinical trial subjects and employees, in our data centers and on our networks. The secure processing, maintenance and transmission of this information is critical to our operations. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or internal bad actors, or breached due to employee error, a technical vulnerability, malfeasance or other disruptions. Although, to our knowledge, we have not experienced any such material security breach to date, any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, significant regulatory penalties, and such an event could disrupt our operations, damage our reputation, and cause a loss of confidence in us and our ability to conduct clinical trials, which could adversely affect our reputation and delay clinical development of our product candidates.

## We may engage in acquisitions that could disrupt our business, cause dilution to our shareholders or reduce our financial resources.

In the future, we may enter into transactions to acquire other businesses, products or technologies. If we do identify suitable candidates, we may not be able to make such acquisitions on favorable terms, or at all. Any acquisitions we make may not strengthen our competitive position, and these transactions may be viewed negatively by customers or investors. We may decide to incur debt in connection with an acquisition or issue our ordinary shares or other equity securities to the shareholders of the acquired company, which would reduce the percentage ownership of our existing shareholders. We could incur losses resulting from undiscovered liabilities of the acquired business that are not covered by the indemnification we may obtain from the seller. In addition, we may not be able to successfully integrate the acquired personnel, technologies and operations into our existing business in an effective, timely and nondisruptive manner. Acquisitions may also divert management attention from day-to-day responsibilities, increase our expenses and reduce our cash available for operations and other uses. We cannot predict the number, timing or size of future acquisitions or the effect that any such transactions might have on our operating results.

The United Kingdom's withdrawal from the European Union may have a negative effect on global economic conditions, financial markets and our business, which could reduce the price of our shares.

Following the vote of a majority of the eligible members of the electorate in the United Kingdom to withdraw from the European Union in a national referendum held on June 23, 2016, the U.K. government served notice under Article 50 of the Treaty of the European Union on March 29, 2017 to formally initiate a withdrawal process. The United Kingdom and the European Union have a two-year period under Article 50 to negotiate the terms for withdrawal. Any extension of the negotiation period for withdrawal will require the consent of all of the remaining 27 member states. The referendum and withdrawal have created significant uncertainty about the future relationship between the United Kingdom and the European Union. Lack of clarity about future U.K. laws and regulations as the United Kingdom determines which EU-derived laws and regulations to replace or replicate as part of a withdrawal, including healthcare and pharmaceutical regulations; financial laws and regulations; tax and free trade agreements; intellectual property rights; supply chain logistics; environmental, health, and safety laws and regulations; immigration laws; and employment laws, could decrease foreign direct investment in the United Kingdom, increase costs, depress economic activity, and restrict our access to capital. If the United Kingdom and the European Union are unable to negotiate acceptable withdrawal terms or if other EU member states pursue withdrawal, barrier-free access between the U.K. and other EU member states or among the European economic area overall could be diminished or eliminated. These developments, or the perception that any of them could occur, have had and may continue to have a significant adverse effect on global economic conditions and the stability of global financial markets, and could significantly reduce global market liquidity and restrict the ability of key market participants to operate in certain financial markets. Asset valuations, currency exchange rates, and credit ratings may be especially subject to increased market volatility. In addition, changes to U.K. border and immigration policy could occur as a result of the United Kingdom's withdrawal from the European Union, affecting our ability to recruit and retain employees from outside the United Kingdom. Any of these factors could have an adverse effect on our business, financial condition, results of operations, and prospects.

Further, the vote for the United Kingdom's withdrawal from the European Union has resulted in a decision to move the EMA from the United Kingdom to the Netherlands, with operations currently scheduled to begin in the Netherlands by end of March 2019. This transition may cause disruption in the administrative and medical scientific links between the EMA and the UK Medicines and Healthcare products Regulatory Agency, or the MHRA, including delays in granting clinical trial authorization or marketing authorization, disruption of importation and export of active substance and other components of new drug formulations, and disruption of the supply chain for clinical trial product and final authorized formulations. The cumulative effects of the disruption to the regulatory framework may add considerably to the development lead time to marketing authorization and commercialization of products in the European Union and/or the United Kingdom.

# Exchange rate fluctuations may adversely affect our results of operations and financial condition.

Owing to the international scope of our operations, fluctuations in exchange rates, particularly between the pound sterling and the U.S. dollar, may adversely affect us. Although some of our operations are based in the United Kingdom, we source research and development, manufacturing, consulting and other services from the United States and the European Union. Further, potential future revenue may be derived from abroad, particularly from the United States. As a result, our business and the market price of our securities may be affected by fluctuations in foreign exchange rates not only between the pound sterling and the U.S. dollar, but also the euro, which may have a significant impact on our results of operations and cash flows from period to period. Currently, we do not have any exchange rate hedging arrangements in place.

## Risks Related to Our Ordinary Shares and this Offering

#### An active trading market for our ordinary shares may not develop.

Prior to this offering, there has been no public market for our ordinary shares. Although we have applied to have our ordinary shares approved for listing on The Nasdaq Global Select Market, or Nasdaq, an active trading market for our shares may never develop or be sustained following this offering. Any delay in the commencement of trading of our ordinary shares on Nasdaq would impair the liquidity of the market for our ordinary shares and make it more difficult for holders to sell their shares. The initial public offering price for our ordinary shares will be determined through negotiations with the underwriters. Among the factors considered in determining the initial public offering price were our future prospects and the prospects of our industry in general, our revenue, net income and certain other financial and operating information in recent periods, and the market prices of securities and certain financial and operating information of companies engaged in activities similar to ours. If an active market for our ordinary shares does not develop, it may be difficult for you to sell shares you purchase in this offering without depressing the market price for the shares, or at all.

# The market price of our ordinary shares may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our ordinary shares in this offering.

Our share price is likely to be volatile. The stock market in general and the market for smaller biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your ordinary shares at or above the initial public offering price. The market price for our ordinary shares may be influenced by many factors, including:

- the success of competitive products or technologies;
- actual or expected changes in our growth rate relative to our competitors;
- results of clinical trials of our product candidates or those of our competitors;
- developments related to our existing or any future collaborations;
- regulatory or legal developments in the United States and other countries;
- · development of new product candidates that may address our markets and make our product candidates less attractive;
- · changes in physician, hospital or healthcare provider practices that may make our product candidates less useful;
- announcements by us, our partners or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- · failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;

- the results of our efforts to discover, develop, acquire or in-license additional product candidates or products;
- · actual or expected changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- · changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions;
- · changes in accounting principles; and
- the other factors described in this "Risk Factors" section and elsewhere in this prospectus.

In addition, the stock market in general, and Nasdaq and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. In the past, when the market price of a security has been volatile, holders of that security have sometimes instituted securities class action litigation against the issuer. If any of the holders of our ordinary shares were to bring such a lawsuit against us, we could incur substantial costs defending the lawsuit and the attention of our senior management would be diverted from the operation of our business. Any adverse determination in litigation could also subject us to significant liabilities. Broad market and industry factors may negatively affect the market price of our ordinary shares, regardless of our actual operating performance. Further, a decline in the financial markets and related factors beyond our control may cause the price of our ordinary shares to decline rapidly and unexpectedly. If the market price of our ordinary shares after the completion of this offering does not exceed the initial public offering price, you may not realize any return on your investment in us and may lose some or all of your investment.

After this offering, our executive officers, directors and principal shareholders, if they choose to act together, will continue to have the ability to control or significantly influence all matters submitted to shareholders for approval.

Upon the closing of this offering, based on the number of ordinary shares outstanding as of April 30, 2018, our executive officers, directors and shareholders who owned more than 5% of our outstanding ordinary shares before this offering and their respective affiliates will, in the aggregate, hold ordinary shares representing approximately 53.0% of our outstanding ordinary shares. In addition, based on the number of ordinary shares outstanding as of April 30, 2018, Kadmon Corporation, LLC owned 16.9% of our outstanding ordinary shares before this offering and is expected to own ordinary shares representing approximately 13.0% of our outstanding voting shares upon the closing of this offering.

As a result, if these shareholders choose to act together, they would be able to control or significantly influence all matters submitted to our shareholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would control or significantly influence the election of directors, the composition of our management and approval of any merger, consolidation, sale of all or substantially all of our assets or other business combination that other shareholders may desire. Any of these actions could adversely affect the market price of our ordinary shares.

Certain of our existing stockholders and their affiliated entities have indicated an interest in purchasing an aggregate of up to approximately \$40.0 million of our ordinary shares in this offering at the initial public offering price per share and on the same terms as the other purchasers in this offering. However, because

indications of interest are not binding agreements or commitments to purchase, the underwriters could determine to sell more, fewer or no shares to any of these potential purchasers, and any of these potential purchasers could determine to purchase more, fewer or no shares in this offering. The foregoing discussion does not reflect any potential purchases by these potential purchasers. See "Principal Shareholders" for more information regarding the ownership of our outstanding ordinary shares by our executive officers, directors and their affiliates.

## If you purchase ordinary shares in this offering, you will suffer immediate dilution of your investment.

The initial public offering price of our ordinary shares will be substantially higher than the net tangible book value per share of our ordinary shares. Therefore, if you purchase our ordinary shares in this offering, you will pay a price per share that substantially exceeds our net tangible book value per share after this offering. To the extent shares subsequently are issued under outstanding options or warrants or to executive officers in connection with this offering, you will incur further dilution. Based on an assumed initial public offering price of \$15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, you will experience immediate dilution of \$11.06 per share as of March 31, 2018, representing the difference between our pro forma as adjusted net tangible book value per share, after giving effect to this offering, and the assumed initial public offering price. In addition, purchasers of ordinary shares in this offering will have contributed approximately 27.0% of the aggregate price paid by all purchasers of our ordinary shares but will own only approximately 18.4% of our ordinary shares outstanding after this offering.

## We have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

Our management will have broad discretion in the application of the net proceeds from this offering and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our ordinary shares. We expect that we will use the net proceeds of this offering to advance our clinical and preclinical programs, develop our gene regulation technology, invest in our vector design and production platform, build-out our internal manufacturing capacity, expand our intellectual property portfolio and pursue additional research and development activities as set forth under "Use of Proceeds." However, our use of these proceeds may differ substantially from our current plans. The failure by our management to apply these funds effectively could result in financial losses that could have a negative impact on our business, cause the price of our ordinary shares to decline and delay the development of our product candidates. Pending their use, we may invest the net proceeds from this offering in a manner that does not produce income or that loses value.

A significant portion of our total outstanding shares are eligible to be sold into the market in the near future, which could cause the market price of our ordinary shares to drop significantly, even if our business is doing well.

Sales of a substantial number of our ordinary shares in the public market, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our ordinary shares. After this offering, we will have outstanding 27,184,140 ordinary shares (or 27,934,140 ordinary shares if the underwriters' exercise their option to purchase additional ordinary shares in full). This includes the shares that we are selling in this offering, which may be resold in the public market immediately without restriction, unless purchased by our affiliates. Substantially all of the remaining 22,184,140 ordinary shares will be restricted as a result of securities laws or lock-up agreements but will become eligible to be sold after this offering as described in the "Shares Eligible for Future Sale" and "Underwriting" sections of this prospectus. Moreover, after this offering, holders of an aggregate of 16,123,234 ordinary shares will have rights, subject to specified conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other shareholders, until such shares can otherwise be sold without restriction under Rule 144 or until the rights terminate pursuant to the terms of the shareholders agreement between us and such holders. We also intend to register 4,669,342 ordinary shares subject to equity awards issued or reserved for future issuance under our equity compensation plans on a registration statement on Form S-8. Once we register these shares, they can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates and the lock-up agreements described above. Any sales of securities by these shareholders could have a negative impact on the trading price of our ordinary shares.

Certain of our existing shareholders and their affiliated entities have indicated an interest in purchasing an aggregate of up to approximately \$40.0 million of our ordinary shares in this offering at the initial public offering price per share. Any such shares purchased by shareholders who are considered to be our affiliates cannot be resold in the public market immediately following this offering as a result of restrictions under securities laws, but will be able to be sold following the expiration of these restrictions as described in the "Shares Eligible for Future Sale."

We are an "emerging growth company," and the reduced disclosure requirements applicable to emerging growth companies may make our ordinary shares less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and may remain an emerging growth company until the last day of the fiscal year following the fifth anniversary of the closing of this offering. However, if certain events occur prior to the end of such five-year period, including if we become a "large accelerated filer," our annual gross revenues exceed \$1.07 billion or we issue more than \$1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure in this prospectus;
- · not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- · reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

We have taken advantage of reduced reporting burdens in this prospectus. In particular, in this prospectus, we have provided only two years of audited financial statements and have not included all of the executive compensation related information that would be required if we were not an emerging growth company. We cannot predict whether investors will find our ordinary shares less attractive if we rely on these exemptions. If some investors find our ordinary shares less attractive as a result, there may be a less active trading market for our ordinary shares and our share price may be reduced or more volatile. In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of these accounting standards until they would otherwise apply to private companies. We have elected to take advantage of this extended transition period.

We will incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, and particularly after we are no longer an emerging growth company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the Nasdaq listing

requirements and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, which in turn could make it more difficult for us to attract and retain qualified members of our board of directors.

We are evaluating these rules and regulations, and cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, we will be required to furnish a report by our management on our internal control over financial reporting. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants, adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing whether such controls are functioning as documented, and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our ordinary shares, our share price and trading volume could decline.

The trading market for our ordinary shares will be influenced by the research and reports that industry or securities analysts publish about us or our business. We do not currently have, and may never obtain, research coverage by securities and industry analysts. If no or few securities or industry analysts commence coverage of us, the trading price for our shares could be negatively impacted. In the event we obtain securities or industry analyst coverage, if any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our share performance, or if any of our preclinical studies or clinical trials and operating results fail to meet the expectations of analysts, our share price would likely decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our share price or trading volume to decline.

Anti takeover provisions in our organizational documents and Cayman Islands law may discourage or prevent a change of control, even if an acquisition would be beneficial to our shareholders, which could depress the price of our ordinary shares and prevent attempts by our shareholders to replace or remove our current management.

Our memorandum and articles of association contain provisions that may discourage unsolicited takeover proposals that shareholders may consider to be in their best interests. Our board of directors is divided into three classes with staggered, three year terms. Our board of directors has the ability to designate the terms of

and issue preferred shares without shareholder approval. We are also subject to certain provisions under Cayman Islands law that could delay or prevent a change of control. Together these provisions may make more difficult the removal of management and may discourage transactions that otherwise could involve payment of a premium over prevailing market prices for our ordinary shares. See "Description of Share Capital."

### There may be difficulties in enforcing foreign judgments against our management or us.

Certain of our directors and management and certain of the other parties named in this prospectus reside outside the United States. A significant portion of our assets and such persons' assets are located outside the United States. As a result, it may be difficult or impossible for investors to effect service of process upon us within the United States or other jurisdictions, including judgments predicated upon the civil liability provisions of the federal securities laws of the United States. See "Enforcement of Civil Liabilities."

In particular, investors should be aware that there is uncertainty as to whether the courts of the Cayman Islands or any other applicable jurisdictions would recognize and enforce judgments of U.S. courts obtained against us or our directors or management as well as against the selling shareholders predicated upon the civil liability provisions of the securities laws of the United States or any state in the United States or entertain original actions brought in the Cayman Islands or any other applicable jurisdictions courts against us or our directors or officers as well as against the selling shareholders predicated upon the securities laws of the United States or any state in the United States.

### The rights of our shareholders differ from the rights typically offered to shareholders of a U.S. corporation.

Our corporate affairs and the rights of holders of ordinary shares are governed by Cayman Islands law, including the provisions of the Cayman Islands Companies Law (2018 Revision), or the Companies Law, the common law of the Cayman Islands and by our memorandum and articles of association. We will also be subject to the federal securities laws of the United States. The rights of shareholders to take action against the directors, actions by minority shareholders and the fiduciary responsibilities of our directors to us under Cayman Islands law are to a large extent governed by the common law of the Cayman Islands. The common law of the Cayman Islands is derived in part from comparatively limited judicial precedent in the Cayman Islands as well as from English common law, the decisions of whose courts are of persuasive authority, but are not binding on a court in the Cayman Islands. The rights of our shareholders and the fiduciary responsibilities of our directors under Cayman Islands law are different from what they would be under statutes or judicial precedent in some jurisdictions in the United States. In particular, the Cayman Islands has a different body of securities laws as compared to the United States, and certain states, such as Delaware, may have more fully developed and judicially interpreted bodies of corporate law. In addition, Cayman Islands companies may not have standing to initiate a shareholders derivative action in a Federal court of the United States. See "Description of Share Capital and Articles of Association—Differences in Corporate Law" in this prospectus for a description of the principal differences between the provisions of the Companies Law applicable to us and, for example, the Delaware General Corporation Law relating to shareholders' rights and protections.

As a result of all of the above, public shareholders may have more difficulty in protecting their interests in the face of actions taken by management, members of the board of directors or controlling shareholders than they would as public shareholders of a United States company.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, shareholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our ordinary shares.

Section 404(a) of the Sarbanes-Oxley Act, or Section 404(a), requires that beginning with our second annual report following our initial public offering, management assess and report annually on the effectiveness of our internal control over financial reporting and identify any material weaknesses in our internal control over

financial reporting. Although Section 404(b) of the Sarbanes-Oxley Act, or Section 404(b), requires our independent registered public accounting firm to issue an annual report that addresses the effectiveness of our internal control over financial reporting, we have opted to rely on the exemptions provided in the JOBS Act, and consequently will not be required to comply with SEC rules that implement Section 404(b) until such time as we are no longer an "emerging growth company."

We expect our first Section 404(a) assessment will take place for our annual report for the fiscal year ending December 31, 2019. Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inadequate internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our ordinary shares.

Because we do not anticipate paying any cash dividends on our ordinary shares in the foreseeable future, capital appreciation, if any, would be your sole source of gain.

Under current U.K. law, a company's accumulated realized profits must exceed its accumulated realized losses (on a non-consolidated basis) before dividends can be paid. Therefore, we must have distributable profits before issuing a dividend. We have never declared or paid any cash dividends on our ordinary shares. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. As a result, capital appreciation, if any, of our ordinary shares would be your sole source of gain on an investment in our ordinary shares for the foreseeable future. See the "Dividend Policy" section of this prospectus for additional information.

#### We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biopharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

We expect to be treated as resident in the United Kingdom for tax purposes, but may be treated as a dual resident company for United Kingdom tax purposes.

It is the intention of our board of directors to conduct our affairs so that the central management and control of the company is exercised in the United Kingdom. As a result, we expect to be treated as resident in the United Kingdom for UK tax purposes. Accordingly, we expect to be subject to UK taxation on our income and gains, except where an exemption applies.

However, we may be treated as a dual resident company for UK tax purposes. As a result, our right to claim certain reliefs from UK tax may be restricted, and changes in law or practice in the United Kingdom could result in the imposition of further restrictions on our right to claim UK tax reliefs.

We may be classified as a passive foreign investment company for U.S. federal income tax purposes, which could result in adverse U.S. federal income tax consequences to U.S. investors in our ordinary shares.

Based on the current and anticipated value of our assets, including goodwill, and the composition of our income, assets and operations, we do not believe we were a "passive foreign investment company," or PFIC, for the taxable year ending on December 31, 2017, and do not expect to be a PFIC for the current taxable year. However, the application of the PFIC rules is subject to uncertainty in several respects, and we cannot assure you that the U.S. Internal Revenue Service, or the IRS, will not take a contrary position. Furthermore, a separate determination must be made after the close of each taxable year as to whether we are a PFIC for that year. Accordingly, we cannot assure you that we were not a PFIC for our taxable year ending on December 31, 2017 and that we will not be a PFIC for our current taxable year or any future taxable year. A non-U.S. company will be considered a PFIC for any taxable year if (i) at least 75% of its gross income is passive income (including interest income), or (ii) at least 50% of the value of its assets (based on an average of the quarterly values of the assets during a taxable year) is attributable to assets that produce or are held for the production of passive income. If we were to be classified as a PFIC for any taxable year during which a U.S. Holder (as defined below under "Material U.S. Federal Income Tax Consequences") holds our ordinary shares, certain adverse U.S. federal income tax consequences could apply to such U.S. Holder, including (i) the treatment of all or a portion of any gain on disposition of our ordinary shares as ordinary income, (ii) the application of a deferred interest charge on such gain and the receipt of certain dividends and (iii) the obligation to comply with certain reporting requirements. See "Material U.S. Federal Income Tax Consequences—Passive Foreign Investment Company Rules."

If a United States person is treated as owning at least 10% of our ordinary shares, such holder may be subject to adverse U.S. federal income tax consequences.

If a U.S. Holder is treated as owning (directly, indirectly or constructively) at least 10% of the value or voting power of our ordinary shares, such U.S. Holder may be treated as a "United States shareholder" with respect to each "controlled foreign corporation" in our group (if any). If our group includes one or more U.S. subsidiaries, certain of our non-U.S. subsidiaries could be treated as controlled foreign corporations (regardless of whether we are treated as a controlled foreign corporation). A United States shareholder of a controlled foreign corporation may be required to report annually and include in its U.S. taxable income its pro rata share of "Subpart F income," "global intangible low-taxed income" and investments in U.S. property by controlled foreign corporations, regardless of whether we make any distributions. An individual that is a United States shareholder with respect to a controlled foreign corporation generally would not be allowed certain tax deductions or foreign tax credits that would be allowed to a United States shareholder that is a U.S. corporation. Failure to comply with these reporting obligations may subject you to significant monetary penalties and may prevent the statute of limitations from starting with respect to your U.S. federal income tax return for the year for which reporting was due. We cannot provide any assurances that we will assist investors in determining whether any of our non-U.S. subsidiaries is treated as a controlled foreign corporation or whether such investor is treated as a United States shareholder with respect to any of such controlled foreign corporations. Further, we cannot provide any assurances that we will furnish to any United States shareholders information that may be necessary to comply with the aforementioned reporting and tax payment obligations. U.S. Holders should consult their tax advisors regarding the potential application of these rules to their investment in our ordinary shares.

# Comprehensive tax reform legislation could adversely affect our business and financial condition.

The U.S. government has recently enacted comprehensive tax legislation that includes significant changes to the taxation of business entities, referenced herein as the Tax Reform Act. These changes include, among others, a permanent reduction to the corporate income tax rate, limiting interest deductions and the use of net operating losses, adopting elements of a territorial tax system and introducing certain anti-base erosion provisions. We continue to examine the impact this tax reform legislation may have on our business. The effect of the Tax Reform Act on our business, whether adverse or favorable, is uncertain, and may not become evident

for some period of time. U.S. Holders should consult their legal and tax advisors regarding any such legislation and the potential tax consequences of investing in our ordinary shares.

Changes in tax laws or challenges to our tax position could adversely affect our results of operations and financial condition.

We are subject to complex tax laws. Changes in tax laws, regulations and treaties, or the interpretation thereof, tax policy initiatives and reforms under consideration and the practices of tax authorities in jurisdictions in which we operate could adversely affect our tax position, including our effective tax rate or tax payments.

In October 2015, the Organization for Economic Co-Operation and Development released a final package of measures to be implemented by member nations in response to a 2013 action plan calling for a coordinated multi-jurisdictional approach to "base erosion and profit shifting" by multinational companies. Multiple member jurisdictions, including the countries in which we operate, have begun implementing recommended changes such as country-by-country reporting requirements and changes to double tax treaties. Additional multilateral changes are anticipated in upcoming years. We often rely on generally available interpretations of applicable tax laws, treaties and regulations. There cannot be certainty that the relevant tax authorities are in agreement with our interpretation of these laws, regulations or treaties, or with tax positions that we have taken. If our interpretation or tax position is challenged by the relevant tax authorities, we could be required to pay taxes that we currently do not collect or pay, may be subject to interest and penalties and there could be an increase to the costs of our services to track and collect such taxes, which could increase our costs of operations or our effective tax rate. Similarly, a tax authority could assert that we are subject to tax in a jurisdiction where we believe we have not established a taxable connection, often referred to as a "permanent establishment" under international tax treaties, and such an assertion, if successful, could increase our expected tax liability in one or more jurisdictions. The occurrence of any of the foregoing tax risks could have a material adverse effect on our business, financial condition and results of operations.

We are unable to predict what national or international tax reform may be proposed or enacted in the future or what effect such changes would have on our business, but such changes, to the extent they are brought into tax legislation, regulations, policies or practices, could impact the tax treatment of our earnings, adversely affect our profitability and increase the complexity, burden and cost of tax compliance.

We have significant net operating losses, or NOLs, and U.K. carryforward tax losses which we may not be able to realize or which may be restricted following the Corporate Reorganization or any future change of control. We also benefit from certain tax incentive regimes, such as research and development tax credits, in the jurisdictions in which we operate and any adverse change to these regimes, the application thereof or challenges to the tax position we have adopted under these regimes could adversely affect our results of operations and financial condition.

As of December 31, 2017, we had federal and state NOL carryforwards in the United States of \$7.8 million and \$7.8 million, respectively, and cumulative carryforward tax losses in the United Kingdom of \$40.0 million, which we expect to be available to reduce future taxable income subject to any relevant restrictions (including those in the UK that limit the percentage of profits that can be reduced by carried forward losses). The U.S. federal and state NOL carry forwards will begin to expire in 2035 and the U.K. carryforward tax losses will continue indefinitely, subject to relevant restrictions, under current UK legislation. Also, as of December 31, 2017, we had research and development credits in the U.S. in the amount of \$697,000.

The NOL carry forwards and U.K. carryforward tax losses are subject to review and possible adjustment by the U.S., U.K. and state tax authorities. NOL carryforwards and U.K. carryforward tax losses may become subject to limitations in the event of certain cumulative changes in the ownership interest of significant shareholders, as defined under Sections 382 Internal Revenue Code, as well as the Corporation Tax Act 2010 Part 14 under the UK tax rules. This could limit the amount of NOLs or carryforward tax losses that we can

utilize annually to offset future taxable income or tax liabilities. Subsequent ownership changes and changes to the UK (or US) tax rules in respect of the utilization of losses carried forward may further affect the limitation in future years.

Additionally, we have not undertaken a study on the completeness of the U.S. research and development credit. As such, the U.S. research and development credits may change and may be subject to review and adjustment by the tax authorities.

#### SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements that can involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this prospectus, including statements regarding our future results of operations and financial position, business strategy, prospective products, product approvals, research and development costs, future revenue, timing and likelihood of success, plans and objectives of management for future operations, future results of anticipated products and prospects, plans and objectives of management are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential," "would" or "continue" or the negative of these terms or other similar expressions. The forward-looking statements in this prospectus are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this prospectus and are subject to a number of risks, uncertainties and assumptions described under the sections in this prospectus entitled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this prospectus. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

You should read this prospectus and the documents that we reference in this prospectus and have filed as exhibits to the registration statement, of which this prospectus is a part, completely and with the understanding that our actual future results may be materially different from what we expect.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this prospectus, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

# INDUSTRY AND OTHER DATA

We obtained the industry, market and competitive position data in this prospectus from our own internal estimates and research as well as from industry and general publications and research, surveys and studies conducted by third parties. Industry publications, studies and surveys generally state that they have been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe that each of these studies and publications is reliable, we have not independently verified market and industry data from third-party sources. While we believe our internal company research as to such matters is reliable and the market definitions are appropriate, neither such research nor these definitions have been verified by any independent source.

#### **USE OF PROCEEDS**

We estimate that the net proceeds to us from our issuance and sale of our ordinary shares in this offering will be approximately \$67.0 million, assuming an initial public offering price of \$15.00 per ordinary share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. If the underwriters' option to purchase additional shares from us is exercised in full, we estimate that our net proceeds will be approximately \$77.5 million. Each \$1.00 increase (decrease) in the assumed initial public offering price of \$15.00 per ordinary share would increase (decrease) the net proceeds to us from this offering by approximately \$4.6 million, assuming that the number of ordinary shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase (decrease) of 1.0 million in the number of ordinary shares we are offering would increase (decrease) the net proceeds to us from this offering by approximately \$13.9 million, assuming that the initial public offering price remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

We anticipate that we will use the net proceeds of this offering for the following purposes:

- approximately \$20 million to \$25 million to further develop our most advanced product candidates, AAV-CNGB3, AAV-CNGB3, AAV-RPGR, AAV-RPE65 and AAV-AQP1;
- approximately \$10 million to \$15 million to scale up our manufacturing facility and related processes;
- approximately \$10 million to \$15 million to fund research and development of our other pipeline product candidates and technologies;
- the remainder, if any, to fund new and ongoing research and development activities and for working capital and other general corporate purposes.

This expected use of the net proceeds from this offering represents our intentions based upon our current plans and business conditions, which could change in the future as our plans and business conditions evolve. We may also use a portion of the net proceeds to in-license, acquire or invest in additional businesses, technologies, products or assets, although currently we have no specific agreements, commitments or understandings in this regard. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the closing of this offering or the amounts that we will actually spend on the uses set forth above. Predicting the cost necessary to develop product candidates can be difficult and we anticipate that we will need additional funds to complete the development of any product candidates we identify. The amounts and timing of our actual expenditures and the extent of clinical development may vary significantly depending on numerous factors, including the progress of our development efforts, the status of and results from preclinical studies and any ongoing clinical trials or clinical trials we may commence in the future, as well as any collaborations that we may enter into with third parties for our product candidates and any unforeseen cash needs. As a result, our management will retain broad discretion over the allocation of the net proceeds from this offering.

Based on our planned use of the net proceeds of this offering and our current cash and cash equivalents, we estimate that such funds will be sufficient to enable us to fund our operating expenses and capital expenditure requirements through the third quarter of 2020. We have based this estimate on assumptions that may prove to be incorrect, and we could use our available capital resources sooner than we currently expect. We may satisfy our future cash needs through the sale of equity securities, debt financings, working capital lines of credit, corporate collaborations or license agreements, grant funding, interest income earned on invested cash balances or a combination of one or more of these sources.

Pending our use of the net proceeds from this offering, we may invest the net proceeds in a variety of capital preservation investments, including short-term, investment-grade, interest-bearing instruments and U.S. government securities.

# DIVIDEND POLICY

We have never declared or paid any cash dividends on our ordinary shares. We intend to retain future earnings, if any, to finance the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future. However, if we do pay a cash dividend on our ordinary shares in the future, we will only pay such dividend out of our profits or share premium (subject to solvency requirements) as permitted under Cayman Islands law.

#### **CAPITALIZATION**

The following table sets forth our cash and cash equivalents and capitalization as of March 31, 2018, as follows:

- on an actual basis reflecting the capitalization of MeiraGTx Limited;
- on a pro forma basis to reflect (a) the Corporation Reorganization described under "Summary—Corporate Reorganization", (b) the conversion of all outstanding preferred shares, including preferred shares issued in connection with the exercise of warrants for cash in an amount equal to \$9.7 million, into ordinary shares prior to the closing of this offering, (c) the reclassification of the related warrant liability into capital in excess of nominal value, and (d) our issuance of 4.7 million preferred shares in April 2018 for aggregate proceeds of \$12.7 million; and
- on a pro forma as adjusted basis to give further effect to (a) the issuance of 1,306,348 ordinary shares (435,450 shares of which will vest upon closing of the offering), which reflects the Executive IPO Grants, plus the accrual of expenses in the amount of \$6.5 million, based on an assumed initial public offering price of \$15.00 per ordinary share, which is the midpoint of the price range set forth on the cover page of this prospectus, related to our obligation to pay associated income taxes incurred by the named executive officers in connection therewith (such \$6.5 million amount representing only one-third of our total obligation to pay income taxes incurred by the named executive officers upon vesting of the Executive IPO Grants, based on an assumed initial public offering price of \$15.00 per ordinary share, which is the midpoint of the price range set forth on the cover page of this prospectus) and (b) our issuance and sale of 5,000,000 ordinary shares in this offering at an assumed initial public offering price of \$15.00 per ordinary share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Our capitalization following the closing of this offering will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing. You should read this information in conjunction with our consolidated financial statements and the related notes appearing at the end of this prospectus and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section and other financial information contained in this prospectus.

		As of March 31, 2018	
	Actual, MeiraGTx Limited	Pro Forma, MeiraGTx Holdings plc	Pro Forma As Adjusted, MeiraGTx Holdings plc(1)
Cash and cash equivalents	\$ 32,356,851	\$ 54,464,388	\$ 121,464,388
Warrant liability	\$ 2,010,225	\$ —	\$ —
Series C preferred shares, \$0.00001 nominal value per share; 9,361,141 shares issued and			
outstanding, actual; no shares, issued and outstanding, pro forma and pro forma as			
adjusted	97,351,080	_	_
Shareholders' (deficit) equity:			
Ordinary shares, \$0.00003881 nominal value per share; 9,336,540 shares issued and			
outstanding, actual; 20,877,792 shares issued and outstanding, pro forma;			
27,184,140 shares issued and 26,313,242 shares outstanding, pro forma as adjusted	364	810	1,055
Capital in excess of nominal value	23,691,708	145,336,087	218,867,607
Accumulated other comprehensive loss	(2,780,242)	(2,780,242)	(2,780,242)
Accumulated deficit	(81,827,196)	(82,003,179)	(95,066,679)
Total shareholders' (deficit) equity	(60,915,366)	60,553,476	121,021,741
Total capitalization	\$ 36,435,714	\$ 60,553,476	\$ 121,021,741

<sup>(1)</sup> Each \$1.00 increase (decrease) in the assumed initial public offering price of \$15.00 per ordinary share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash and cash equivalents, capital in excess of nominal value, total shareholders' equity and total capitalization by \$4.6 million, assuming that the number of ordinary shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase (decrease) of 1.0 million in the number of ordinary shares offered by us at the assumed initial public offering price per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash and cash equivalents, capital in excess of nominal value, total shareholders' equity and total capitalization by approximately \$13.9 million.

The number of shares in the table above includes 37,270 unvested restricted shares and does not include:

- 1,614,346 ordinary shares issuable upon exercise of share options outstanding under our 2016 Plan as of March 31, 2018, at a weighted-average exercise price of \$5.32 per ordinary share;
- 3,054,996 ordinary shares reserved for future issuance under our 2018 Plan, which will become effective in connection with this offering, as well as any automatic increases in the number of our ordinary shares reserved for future issuance under the 2018 Plan; and
- 509,166 ordinary shares reserved for future issuance under our 2018 ESPP, which will become effective in connection with this offering, as well as any automatic increases in the number of our ordinary shares reserved for future issuance under our 2018 ESPP.

#### DILUTION

If you invest in our ordinary shares in this offering, your ownership interest will be immediately diluted to the extent of the difference between the initial public offering price per ordinary share and the pro forma as adjusted net tangible book value per ordinary share after this offering.

As of March 31, 2018, we had a historical net tangible book value of \$22.4 million, or \$2.40 per ordinary share. Our historical net tangible book value per share represents total tangible assets less total liabilities, divided by the number of our ordinary shares outstanding as of March 31, 2018.

Our pro forma net tangible book value as of March 31, 2018 was \$46.6 million, or \$2.23 per ordinary share. Pro forma net tangible book value represents the amount of our total tangible assets less total liabilities, after giving effect to (a) the Corporate Reorganization described under "Summary—Corporate Reorganization", (b) the conversion of all outstanding preferred shares, including preferred shares issued in connection with the exercise of warrants for cash in an amount equal to \$9.7 million, into ordinary shares prior to the closing of this offering, (c) the reclassification of the related warrant liability into capital in excess of nominal value, and (d) our issuance of 4.7 million preferred shares in April 2018 for aggregate proceeds of \$12.7 million. Pro forma net tangible book value per ordinary share represents our pro forma net tangible book value divided by the total number of ordinary shares outstanding as of March 31, 2018, after giving effect to the pro forma adjustment described above.

After giving further effect to (a) the issuance of the Executive IPO Grants plus the accrual of expenses in the amount of \$6.5 million, based on an assumed initial public offering price of \$15.00 per ordinary share, which is the midpoint of the price range set forth on the cover page of this prospectus, related to our obligation to pay associated income taxes incurred by the named executive officers (such \$6.5 million amount representing only one-third of our total obligation to pay income taxes incurred by the named executive officers upon vesting of the Executive IPO Grants, based on an assumed initial public offering price of \$15.00 per ordinary share, which is the midpoint of the price range set forth on the cover page of this prospectus) and (b) receipt of the net proceeds from our issuance and the sale of 5,000,000 ordinary shares in this offering at an assumed initial public offering price of \$15.00 per ordinary share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of March 31, 2018 would have been approximately \$107.1 million, or approximately \$3.94 per ordinary share. This amount represents an immediate increase in pro forma net tangible book value of \$1.70 per ordinary share to our existing shareholders and an immediate dilution of approximately \$11.06 per ordinary share to new investors participating in this offering. We determine dilution by subtracting the pro forma as adjusted net tangible book value per ordinary share after this offering from the amount of cash that a new investor paid for an ordinary share. The following table illustrates this dilution:

Assumed initial public offering price per ordinary share		\$15.00
Historical net tangible book value per ordinary share as of March 31, 2018	\$ 2.40	
Decrease per ordinary share attributable to the conversion of		
our preferred shares	(0.17)	
Pro forma net tangible book value per ordinary share as of March 31, 2018	2.23	
Increase per ordinary share attributable to this offering	1.70	
Pro forma as adjusted net tangible book value per ordinary share after this offering		3.94
Dilution per ordinary share to new investors in this offering		\$11.06
our preferred shares Pro forma net tangible book value per ordinary share as of March 31, 2018 Increase per ordinary share attributable to this offering Pro forma as adjusted net tangible book value per ordinary share after this offering	· · · · · · · · · · · · · · · · · · ·	3.9 <sup>2</sup> \$11.06

Each \$1.00 increase (decrease) in the assumed initial public offering price of \$15.00 per ordinary share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted net tangible book value per ordinary share after this offering by \$0.17, and dilution in

pro forma net tangible book value per ordinary share to new investors by \$0.17, assuming that the number of ordinary shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase of 1.0 million in the number of ordinary shares offered by us would increase our pro forma as adjusted net tangible book value per ordinary share after this offering by \$0.36 per ordinary share and decrease the dilution to new investors by \$0.36 per ordinary share, assuming that the assumed initial public offering price remains the same, and after deducting the estimated underwriting discounts and commissions and the estimated offering expenses payable by us. A decrease of 1.0 million in the number of ordinary shares offered by us would decrease our pro forma as adjusted net tangible book value per ordinary share after this offering by \$0.39 per ordinary share and increase the dilution to new investors by \$0.39 per ordinary share, assuming that the assumed initial public offering price remains the same, and after deducting the estimated underwriting discounts and commissions and the estimated offering expenses payable by us.

If the underwriters exercise their option to purchase additional ordinary shares in full, the pro forma as adjusted net tangible book value after this offering would be \$4.21 per ordinary share, the increase in pro forma net tangible book value per ordinary share would be \$0.30 and the dilution per share to new investors would be \$10.79 per ordinary share, in each case assuming an initial public offering price of \$15.00 per ordinary share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting the estimated underwriting discounts and commissions and the estimated offering expenses payable by us.

The following table summarizes the pro forma as adjusted basis described above, as of March 31, 2018, the differences between the number of ordinary shares purchased from us, the total consideration paid to us in cash and the average price per share that existing shareholders and new investors paid. The calculation below is based on an assumed initial public offering price of \$15.00 per ordinary share, which is the midpoint of the price range set forth on the cover page of this prospectus, before deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

	Shares Purchased		Total Consideration		Aver	age Price
	Number	Percent	Number	Percent	Pe	r Share
Existing shareholders	22,184,140	81.6%	\$128,742,388	63.2%	\$	5.80
New investors	5,000,000	18.4	75,000,000	36.8	\$	15.00
Total	27,184,140	100.0%	\$203,742,388	100.0%		

Certain of our existing shareholders and their affiliated entities have indicated an interest in purchasing an aggregate of up to approximately \$40.0 million of our ordinary shares in this offering at the initial public offering price per share and on the same terms as the other purchasers in this offering. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could determine to sell more, fewer or no shares to any of these potential purchasers, and any of these potential purchasers could determine to purchase more, fewer or no shares in this offering. The table above does not reflect any potential purchases by these potential purchasers.

The foregoing tables and calculations are based on the number of our ordinary shares outstanding as of March 31, 2018 (which included 37,270 unvested restricted shares subject to repurchase), after giving effect to the automatic conversion of all preferred shares into ordinary shares in connection with this offering, and exclude:

- 1,614,346 ordinary shares issuable upon exercise of share options outstanding under our 2016 Plan as of March 31, 2018, at a weighted-average exercise price of \$5.32 per share;
- 3,054,996 additional ordinary shares reserved for future issuance under our 2018 Plan, which will become effective in connection with
  this offering, as well as any automatic increases in the number of our ordinary shares reserved for future issuance under the 2018 Plan;
  and

• 509,166 ordinary shares reserved for future issuance under our 2018 ESPP, which will become effective in connection with this offering, as well as any automatic increases in the number of our ordinary shares reserved for future issuance under our 2018 ESPP.

To the extent any of these outstanding options is exercised, there will be further dilution to new investors. If all of such outstanding options had been exercised as of March 31, 2018, the pro forma as adjusted net tangible book value per ordinary share after this offering would be \$4.01, and total dilution per ordinary share to new investors would be \$10.99.

If the underwriters exercise their option to purchase additional ordinary shares in full:

- the percentage of our ordinary shares held by existing shareholders will decrease to approximately 79.4% of the total number of our
  ordinary shares outstanding after this offering; and
- the number of shares held by new investors will increase to 5,750,000, or approximately 20.6% of the total number of our ordinary shares outstanding after this offering.

# SELECTED CONSOLIDATED FINANCIAL DATA

The following tables present our selected consolidated financial as of the dates and for the periods indicated. We have derived the consolidated statement of operations and comprehensive loss data for the years ended December 31, 2016 and 2017 from our audited consolidated financial statements appearing at the end of this prospectus. We have derived the consolidated balance sheet data as of March 31, 2018 and the consolidated statement of operations and comprehensive loss data for the three months ended March 31, 2017 and 2018 from our unaudited financial statements included elsewhere in this prospectus. These unaudited financial statements have been prepared on a basis consistent with our audited financial statements and, in our opinion, contain all adjustments, consisting of normal and recurring adjustments, necessary for the fair presentation of such financial data.

Our historical results are not necessarily indicative of the results that should be expected in any future period. You should read the following selected consolidated financial data together with our consolidated financial statements and the related notes appearing at the end of this prospectus and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section of this prospectus

	Year Ended December 31,			Ended March 31,
Consolidated Statement of One systimus and Communication I are Date.	2016	2017	2017	2018
Consolidated Statement of Operations and Comprehensive Loss Data:				
Operating expenses:	ф сорс <b>т</b> ро	ф. 0 DDE 04E	Ф D 4 40 E 40	ф. 11.1DD 01.0
General and administrative	\$ 6,026,529	\$ 9,325,017	\$ 2,148,540	\$ 11,122,016
Research and development	14,037,918	22,359,712	4,823,357	6,927,322
Total operating expenses	20,064,447	31,684,729	6,971,897	18,049,338
Loss from operations	(20,064,447)	(31,684,729)	(6,971,897)	(18,049,338)
Other non-operating income (expense):				
Foreign currency gain	265,543	1,676,117	149,249	978,624
Convertible note inducement	_	(553,500)	_	_
Change in fair market value of warrant liability	_	(465,633)	_	669,408
Interest income	32,068	26,073	10,389	25,308
Interest expense	(25,440)	(42,863)	(8,126)	(27,355)
Net loss	(19,792,276)	(31,044,535)	(6,820,385)	(16,403,353)
Net loss attributable to non-controlling interest in subsidiary	305,883			
Net loss attributable to MeiraGTx shareholders	(19,486,393)	(31,044,535)	(6,820,385)	(16,403,353)
Other comprehensive loss	(671,391)	(1,361,365)	(130,895)	(757,765)
Comprehensive loss	(20,157,784)	(32,405,900)	(6,951,280)	(17,161,118)
Less: comprehensive loss (income) attributable to non-controlling				
interest	8,520	_	_	_
Comprehensive loss attributable to MeiraGTx shareholders	\$(20,149,264)	\$ (32,405,900)	\$(6,951,280)	\$ (17,161,118)
Net loss attributable to MeiraGTx ordinary shareholders	\$(19,486,393)	\$ (31,044,535)	\$(6,820,385)	\$ (16,403,353)
Accretion on Series C preferred shares	(85,425)	(806,963)	(22,761)	(664,718)
Adjusted net loss attributable to MeiraGTx ordinary shareholders	\$(19,571,818)	\$ (31,851,498)	\$(6,843,146)	\$ (17,068,071)

	Year Ended I	December 31,	Three Months Ended March 31,		
	2016	2017	2017	2018	
Basic and diluted net loss per ordinary share attributable to					
ordinary shareholders(1)	\$ (0.63)	\$ (0.96)	\$ (0.21)	\$ (0.49)	
Weighted-average number of ordinary shares outstanding—					
basic and diluted(1)	31,098,591	33,269,157	32,851,408	34,647,368	

<sup>(1)</sup> See Note 12 to our consolidated financial statements included elsewhere in this prospectus for an explanation of the method used to calculate the historical basic and diluted net loss per ordinary share and the weighted-average number of shares used in the computation of the per share amounts. Shares outstanding does not give effect to the anticipated 1 for 3.881 reverse share split (by way of consolidation of the share capital of the Company) described elsewhere in this prospectus.

	As of Dece	As of December 31,		
	2016	2017	2018	
Consolidated Balance Sheet Data:				
Cash and cash equivalents	\$ 17,476,641	\$ 8,548,638	\$ 32,356,851	
Total assets	\$ 22,551,149	\$ 25,854,219	\$ 50,780,903	
Total liabilities	\$ 6,856,572	\$ 21,880,853	\$ 14,345,189	
Convertible preferred C shares	\$ 32,833,660	\$ 51,338,631	\$ 97,351,080	
Total shareholders' deficit	\$(17,139,083)	\$ (47,365,265)	\$ (60,915,366)	

# MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of financial condition and operating results together with the section captioned "Selected Financial Data" and our financial statements and the related notes appearing at the end of this prospectus. This discussion contains forward-looking statements that involve risks and uncertainties. As a result of many factors, such as those set forth in the section of the prospectus captioned "Risk Factors" and elsewhere in this prospectus, our actual results may differ materially from those anticipated in these forward-looking statements. For convenience of presentation some of the numbers have been rounded in the text below.

MeiraGTx Holdings plc was incorporated under the laws of the Cayman Islands to become the holding company of our business pursuant to our Corporate Reorganization. Prior to this offering, MeiraGTx Holdings plc will have only engaged in activities incidental to its formation, the Corporate Reorganization and this offering. Accordingly, financial information for MeiraGTx Holdings plc and a discussion and analysis of its results of operations and financial condition for the period of its operations prior to the Corporate Reorganization would not be meaningful and are not presented. Following the Corporate Reorganization, our financial statements will present the results of operations of MeiraGTx Holdings plc and its consolidated subsidiaries.

#### Overview

We are a vertically integrated, clinical stage gene therapy company with four ongoing clinical programs and a broad pipeline of preclinical and research programs. We have core capabilities in viral vector design and optimization, gene therapy manufacturing as well as a potentially transformative gene regulation technology. Led by an experienced management team, we have taken a portfolio approach by licensing, acquiring and developing technologies that give us depth across both product candidates and indications. Though initially focusing on the eye, salivary gland and central nervous system, we intend to expand our focus in the future to develop additional gene therapy treatments for patients suffering from a range of serious diseases.

We are a private limited company incorporated under the laws of England and Wales, and were formed and commenced operations in 2015. Our discussion of our financial condition and results of operations is based upon our financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States. Since our formation, we have devoted substantially all of our resources to developing our technology platform, establishing our viral vector manufacturing facility and developing manufacturing processes, advancing the product candidates in our ophthalmology, salivary gland and neurodegenerative disease programs, building our intellectual property portfolio, organizing and staffing our company, business planning, raising capital, and providing general and administrative support for these operations. In 2016, we completed the acquisition of assets held by BRI-Alzan, Inc., a Delaware corporation, including a worldwide license agreement to develop certain preclinical technology for the treatment of ALS. To date, we have financed our operations primarily with cash on hand and proceeds from the sales of our Series C preferred shares and Series A ordinary shares. Through March 31, 2018, we received gross proceeds of approximately \$97.6 million from sales of our Series C preferred shares. In addition, from April 1, 2018 through April 30, 2018, we issued 1,212,697 Series C preferred shares for gross proceeds of \$12.7 million. As of April 30, 2018, we had cash and cash equivalents of \$39.8 million.

We are a clinical stage company and have not generated any product revenues to date. We have four clinical programs and a pipeline of preclinical programs. Since inception, we have incurred significant operating losses. Our net losses for the three months ended March 31, 2017 and 2018 were \$6.8 million and \$16.4 million, respectively, and for the years ended December 31, 2016 and 2017 were \$19.5 million and \$31.1 million, respectively. As of March 31, 2018, we had an accumulated deficit of \$81.8 million. We do not expect to generate revenue from sales of any products for several years, if at all.

Our total operating expenses were \$7.0 million and \$18.0 million for the three months ended March 31, 2017 and 2018, respectively, and were \$20.1 million and \$31.7 million for the years ended December 31, 2016 and 2017, respectively. We expect our operating expenses to increase substantially in connection with our ongoing development activities related to our product candidates. We anticipate that our expenses will increase due to costs associated with our clinical development program targeting in achromatopsia due to mutations in the *CNGB3* or *CNGA3* gene, inherited retinal dystrophy caused by mutations in *RPE65*, or *RPE65*-deficiency, and X-Linked retinitis pigmentosa, or XLRP. In addition, we expect to incur increasing costs associated with our clinical activities for *hAQP1* for the treatment of radiation-induced xerostomia. We also expect to incur expenses related to research activities in additional therapeutic areas to expand our pipeline, hiring additional personnel in manufacturing, research, clinical trials, quality and other functional areas, and associated cash and share-based compensation expense, as well as the further development of internal manufacturing capabilities and capacity and other associated costs including the management of our intellectual property portfolio. In addition, upon the closing of this offering, we expect to incur additional costs associated with operating as a public company.

As a result of these anticipated expenditures, we will require additional capital beyond the proceeds of this offering, which we may raise through equity offerings, debt financings, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements or other sources to enable us to complete the development and potential commercialization of our product candidates. Furthermore, upon closing of this offering, we expect to incur additional costs associated with being a public company. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative effect on our financial condition and our ability to pursue our business strategy. In addition, attempting to secure additional financing may divert the time and attention of our management from day-to-day activities and harm our product candidate development efforts. If we are unable to raise capital when needed or on acceptable terms, we would be forced to delay, reduce or eliminate certain of our research and development programs.

Based on our planned use of the net proceeds of this offering and our current cash and cash equivalents, we estimate that such funds will be sufficient to enable us to fund our operating expenses and capital expenditure requirements through the third quarter of 2020. We have based these estimates on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. See "—Liquidity and Capital Resources." Because of the numerous risks and uncertainties associated with the development of our product candidates, any future product candidates, our platform and technology and because the extent to which we may enter into collaborations with third parties for development of any of our product candidates is unknown, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the research and development of our product candidates. Our future capital requirements will depend on many factors, including:

- · the initiation, progress, timing, costs and results of our planned clinical trials for our product candidates;
- · the outcome, timing and cost of meeting regulatory requirements established by the FDA, EMA and other regulatory authorities;
- the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- the cost of defending potential intellectual property disputes, including patent infringement actions brought by third parties against us or any of our product candidates;
- the effect of competing technological and market developments;
- the costs and timing of further developing our manufacturing facilities in the United Kingdom;
- the costs of operating as a public company.

- the extent to which we in-license or acquire other products and technologies;
- the cost of establishing sales, marketing and distribution capabilities for our product candidates in regions where we choose to commercialize our products; and
- the initiation, progress, timing and results of our commercialization of our product candidates, if approved for commercial sale.

Adequate additional funds may not be available to us on acceptable terms, or at all. To the extent that we raise additional capital through the sale of equity or convertible securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a shareholder. Any future debt financing or preferred equity or other financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends and may require the issuance of warrants, which could potentially dilute your ownership interests.

If we raise additional funds through collaborations, strategic alliances, or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce, or terminate our product development programs or any future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Because of the numerous risks and uncertainties associated with drug development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate revenue from product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

#### **Components of Our Results of Operations**

# **Operating Expenses**

Our operating expenses since inception have consisted primarily of general and administrative costs and research and development costs.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and other related costs, including share-based compensation, for personnel in our executive, finance, business development and administrative functions. General and administrative expenses also include legal fees relating to intellectual property and corporate matters; professional fees for accounting, auditing, tax and consulting services; insurance costs; travel expenses; and office facility-related expenses, which include direct depreciation costs.

We expect that our general and administrative expenses will increase in the future as we increase our personnel headcount to support increased research and development activities. We also expect to incur increased expenses associated with being a public company, including costs of accounting, audit, legal, regulatory and tax-related services associated with maintaining compliance with Nasdaq and SEC requirements; director and officer insurance costs; and investor and public relations costs.

# Research and Development Expenses

Research and development expenses consist primarily of costs incurred for our research activities, including our discovery efforts, and the development of our product candidates, and include:

- employee-related expenses, including salaries, benefits and travel of our research and development personnel;
- expenses incurred in connection with third-party vendors that conduct clinical and preclinical studies and manufacture the drug product for the clinical trials and preclinical activities;
- · acquisition of in-process research and development;
- costs associated with clinical and preclinical activities including costs related to facilities, supplies, rent, insurance, certain legal fees, share-based compensation, and depreciation; and
- expenses incurred with the development and operation of our manufacturing facility.

We expense research and development costs as incurred.

We typically use our employee and infrastructure resources across our development programs. We track outsourced development costs by product candidate or development program, but we do not allocate personnel costs, license payments made under our licensing arrangements or other internal costs to specific development programs or product candidates. These costs are included in other research and development expenses in the table below.

The following table summarizes our research and development expenses:

		Year Ended December 31,			Three Months Ended March 31,		
	2016	2017	Change	2017	2018	Change	
Ophthalmology programs	\$ 2,026,592	\$ 4,133,015	\$2,106,423	\$ 766,505	\$1,465,179	\$ 698,674	
Salivary gland programs	967,745	913,706	(54,039)	225,101	211,215	(13,886)	
Neurodegenerative diseases programs	922,127	2,220,843	1,298,716	425,737	604,518	178,781	
Manufacturing	379,656	3,213,861	2,834,205	275,868	792,387	516,519	
Other research and development costs	9,741,798	11,878,287	2,136,489	3,130,144	3,854,023	723,879	
Total research and development expenses	\$14,037,918	\$22,359,712	\$8,321,794	\$4,823,355	\$6,927,322	\$2,103,967	

Research and development activities are central to our business model. We expect that our research and development expenses will continue to increase substantially for the foreseeable future as we initiate additional preclinical and clinical trials of our existing product candidates and continue to discover and develop additional product candidates.

We cannot determine with certainty the duration and costs of future clinical trials of our product candidates or any other product candidate we may develop or if, when, or to what extent we will generate revenue from the commercialization and sale of any product candidate for which we obtain marketing approval. We may never succeed in obtaining marketing approval for any product candidate. The duration, costs and

timing of clinical trials and development of our existing product candidates or any other product candidate we may develop will depend on a variety of factors, including:

- the scope, rate of progress, expense and results of clinical trials of our existing product candidates, as well as of any future clinical trials of other product candidates and other research and development activities that we may conduct;
- uncertainties in clinical trial design and patient enrollment rates;
- the actual probability of success for our product candidates, including the safety and efficacy, early clinical data, competition, manufacturing capability and commercial viability;
- · significant and changing government regulation and regulatory guidance;
- the timing and receipt of any marketing approvals; and
- · the expense of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA or another U.S. or foreign regulatory authority were to require us to conduct clinical trials beyond those that we anticipate will be required for the completion of clinical development of a product candidate, or if we experience significant delays in our clinical trials due to patient enrollment or other reasons, we would be required to expend significant additional financial resources and time on the completion of clinical development.

# Other non-operating income (expense)

Other non-operating income (expense) includes the following:

Foreign currency gain

Our consolidated financial statements are presented in U.S. dollars, which is our reporting currency. The financial position and results of operations of our subsidiaries MeiraGTx UK II and MeiraGTx B.V. are measured using the foreign subsidiaries' local currency as the functional currency. MeiraGTx UK II cash accounts holding U.S. dollars are remeasured based upon the exchange rate at the date of remeasurement with the resulting gain or loss included in the consolidated statement of operations and comprehensive loss. Expenses of such subsidiaries have been translated into U.S. dollars at average exchange rates prevailing during the period. Assets and liabilities have been translated at the rates of exchange on the consolidated balance sheet date. The resulting translation gain and loss adjustments are recorded directly as a separate component of shareholders' equity and as other comprehensive loss on the consolidated statement of operations and comprehensive loss.

Convertible note inducement expense

Convertible note inducement expense consists of the issuance of a warrant to a convertible note holder as an inducement to convert the note payable into Series C preferred shares.

Change in fair value of warrant liability

We have determined that our warrants are classified as liabilities on our balance sheet because the Series C preferred shares underlying the warrants have a redemption feature in the event of a change of control of the

Company. The fair values of the warrants are estimated using the Black-Scholes valuation model with certain assumptions regarding risk free interest rate, expected volatility, expected divided yield and expected life. The Black-Scholes value of the warrants was recorded as a warrant liability and is remeasured quarterly. Any changes in the quarterly valuation of the warrants is charged to operations.

#### **Critical Accounting Policies and Use of Estimates**

Our management's discussion and analysis of financial condition and results of operations is based on our financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of our financial statements and related disclosures requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, costs and expenses and the disclosure of contingent assets and liabilities in our financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in the notes to our financial statements appearing at the end of this prospectus, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our financial statements.

#### Consolidation

Our consolidated financial statements include the accounts of MeiraGTx Limited and its wholly owned subsidiaries, MeiraGTx, LLC, a Delaware limited liability company, BRI-Alzan, Inc., a Delaware corporation, (the assets of which we acquired in 2016, as described above), MeiraGTx B.V., a Netherlands corporation, and MeiraGTx UK Limited, a limited company incorporated under the laws of England and Wales. The consolidated financial statements also include the accounts of MeiraGTx UK II Limited, a limited company incorporated under the laws of England and Wales, which was a 60% owned subsidiary from April 27, 2015 through April 8, 2016. On April 8, 2016, we acquired the remaining 40% of interest in MeiraGTx UK II Limited.

All intercompany balances and transactions between the consolidated companies have been eliminated in consolidation.

### Foreign Currencies

Our consolidated financial statements are presented in U.S. dollars, our reporting currency. The financial position and results of operations of MeiraGTx UK II and MeiraGTx UK II cash accounts holding U.S. dollars are remeasuring based upon the exchange rate at the date of remeasurement with the resulting gain or loss included in the consolidated statement of operations and comprehensive loss. Expenses of such subsidiaries have been translated into U.S. dollars at average exchange rates prevailing during the period. Assets and liabilities have been translated at the rates of exchange on the consolidated balance sheet dates. The resulting translation gain and loss adjustments are recording directly as a separate component of shareholders' equity and as other comprehensive loss on the consolidated statements of operations and comprehensive loss.

# Income Taxes

Since our inception in 2015, we have not recorded any U.K. or U.S. federal or state income tax benefits for the net losses we have incurred in any year or for our U.S. research and development tax credits, due to our uncertainty of realizing a benefit from those items. As of December 31, 2017, we had U.S. federal and state net operating loss carryforwards of \$7.8 million and \$7.8 million, respectively, each of which begin to expire in 2035. We also had U.K. net operating loss carryforwards of \$40.0 million, which will continue indefinitely under current U.K. legislation.

# Research and Development

Research and development costs are charged to expense as incurred. These costs include, but are not limited to, employee-related expenses, including salaries, benefits and travel of our research and development personnel; expenses incurred under agreements with contract research organizations and investigative sites that conduct clinical and preclinical studies and manufacture the drug product for the clinical studies and preclinical activities; acquisition of in-process research and development; facilities; supplies; rent, insurance, certain legal fees, stock-based compensation, depreciation and other costs associated with clinical and preclinical activities and regulatory operations. Refundable research and development tax credits received are recorded as an offset to these costs.

Costs for certain development activities, such as outside research programs funded by us, are recognized based on an evaluation of the progress to completion of specific tasks with respect to their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the financial statements as prepaid or accrued research and development expense, as the case may be.

# **Share-Based Compensation**

**Options** 

We grant share options to employees, non-employee members of our board of directors and non-employee consultants as compensation for services performed. Employee and non-employee members of the board of directors' awards of share-based compensation are accounted for in accordance with ASC 718, Compensation—Stock Compensation, or ASC 718. ASC 718 requires all share-based payments to employees and non-employee directors, including grants of share options, to be recognized in the statement of operations and comprehensive loss based on their grant date fair values. The grant date fair value of share options is estimated using the Black-Scholes option valuation model.

Using this model, fair value is calculated based on assumptions with respect to (i) the fair value our ordinary shares on the grant date; (ii) expected volatility of our ordinary share price, (iii) the periods of time over which employees and members of our board of directors are expected to hold their options prior to exercise (expected term), (iv) expected dividend yield on our ordinary shares, and (v) risk-free interest rates.

Our ordinary shares have not been traded on a public exchange. Therefore, we do not have sufficient company-specific information available to determine the expected term based on its historical data. As a result, the expected term of share options granted to employees and members of our board of directors is determined using the average of the vesting period and contractual life of the option, an accepted method for our option grants under the SEC's Staff Accounting Bulletin No. 107 and No. 110, Share-Based Payment.

Similarly, we believe that our future volatility will differ materially during the expected term from the volatility that would be calculated from our historical share prices to date. Consequently, expected volatility is based on an analysis of guideline companies in accordance with ASC 718. The expected dividend yield is zero as we have never paid dividends and do not currently anticipate paying any in the foreseeable future. Risk-free interest rates are based on quoted U.S. Treasury rates for securities with maturities approximating the option's expected term.

As of January 1, 2016, we early adopted ASU 2016-09, Improvements to Employee Share-Based Payment Accounting, and accounts for forfeitures as they occur from that date. Additionally, excess tax benefits and deficiencies will be recognized as income tax expense or benefit in the income statement. There was no cumulative effect adjustment as we did not issue any options prior to January 1, 2016.

We account for options granted to non-employee consultants under ASC 505-50, Equity-Based Payments to Non-Employees. As such, we estimate the fair value of each such option using the Black-Scholes model, with the expected term of share options granted to non-employees initially equal to the options' maximum contractual life of ten years, at issuance. On each subsequent reporting date until performance is complete, we revalue all outstanding options granted to non-employee consultants during the vesting period of each tranche. Under ASC 505-50, upon re-measurement of each award, income or expense is recognized during its vesting term. Compensation cost relating to awards with service-based graded vesting schedules is recognized as general and administrative and research and development expenses in the consolidated statement of operations and comprehensive loss using the straight-line method.

#### Restricted Shares

In connection with certain service agreements and research agreements, we have granted restricted Ordinary Shares as compensation. The shares are recognized in the statement of operations and comprehensive loss based on their grant date fair values. Compensation cost relating to share grants with service-based graded vesting schedules is recognized based on the vesting schedule.

# **Determination of Fair Value of Ordinary Shares**

As there has been no public market for our ordinary shares to date, the estimated fair value of our ordinary shares has been determined by our board of directors as of the date of each option grant, with input from management, considering our most recently available third-party valuations of ordinary shares and our board of directors' assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent valuation through the date of the grant.

Third-party valuations were performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation. The third party estimated the fair value of the equity value of our company using a special case of the market approach known as the backsolve method. The backsolve method was used to solve for the implied total equity value based on our issuances of Series C preferred shares. Consideration was given to the rights and preferences of each of our classes of equity and the expected time to a liquidity event. An option pricing allocation method, or OPM, was selected to allocate the total equity value. The OPM treats ordinary shares and preferred shares as call options on the total equity value of a company, with exercise prices based on the value thresholds at which the allocation among the various holders of a company's securities changes. Under this method, the ordinary shares have value only if the funds available for distribution to shareholders exceeded the value of the preferred share liquidation preference at the time of the liquidity event, such as a strategic sale or a merger. These third-party valuations resulted in a valuation of our ordinary shares of \$7.57, \$2.64, \$5.63 and \$6.02 per share as of December 31, 2016, September 15, 2017, December 31, 2017 and March 31, 2018, respectively.

The decrease in the valuation from December 31, 2016 to September 15, 2017 was due primarily to the Company decreasing the offering price of the Series C preferred shares from \$20.96 per share at December 31, 2016 to \$10.48 per share at September 15, 2017. Additionally, warrants were issued in connection with the issuance of Series C preferred shares at that time.

In addition to considering the results of these third-party valuations, our board of directors considered various objective and subjective factors to determine the fair value of our ordinary shares as of each grant date, including:

- the prices at which we sold Series C preferred shares and the superior rights and preferences of the Series C preferred shares relative to our ordinary shares at the time of each grant;
- the progress of our research and development programs, including the status and results of clinical trials and preclinical studies for our product candidates;

- our stage of development and commercialization and our business strategy;
- external market conditions affecting the biopharmaceutical industry and trends within the biopharmaceutical industry;
- · our financial position, including cash on hand, and our historical and forecasted performance and operating results;
- the lack of an active public market for our ordinary shares and our Series C preferred shares;
- the likelihood of achieving a liquidity event, such as an initial public offering, or IPO, or sale of our company in light of prevailing market conditions; and
- · the analysis of IPOs and the market performance of similar companies in the biopharmaceutical industry.

The assumptions underlying these valuations represented management's best estimate, which involved inherent uncertainties and the application of management's judgment. As a result, if we had used different assumptions or estimates, the fair value of our ordinary shares and our share-based compensation expense could have been materially different.

# **Warrant Liability**

During 2017, we issued warrants to purchase Series C preferred shares to certain investors. Due to the potential redemption feature of the underlying Series C preferred shares, the warrants have been classified as a liability. Liability accounting requires that the fair value of warrants be remeasured each reporting period with changes recorded in the statement of operations and comprehensive loss. These warrants to purchase Series C preferred shares will remain outstanding until the exercise or expiration of the warrants or the completion of this offering, at which time the warrant liability will be remeasured to fair value and reclassified to capital in excess of nominal value.

For the unobservable inputs for the warrants, the expected volatility was determined at each measurement date by taking an average of the volatility of other publicly traded peer biotechnology companies.

The expected life was determined at each measurement date based upon our estimate of the time until the Company has a conversion event, as described in Note 11 of our consolidated financial statements included elsewhere in this prospectus. The fair value of the Series C preferred shares were based upon recent issuances of our Series C preferred shares on or about these dates.

The estimated fair values of our warrants are not necessarily indicative of the amounts that would be realized in a current market exchange. The determination of the fair value of the warrants are sensitive to changes in in the assumptions used and a change in those inputs could result in a significantly higher or lower fair value measurement. If the volatility were to increase or the expected life were to increase, the fair value of the warrants would increase. Conversely, if the volatility were to decrease or the expected life were to decrease, the fair value of the warrants would decrease.

# Series C preferred shares

The Series C preferred shares are not redeemable. However in the event of a Sale (as defined in the Articles of Association), which would include a change of control that is outside of our control, the Series C preferred shares are entitled to receive a payment which is equal to their liquidation value. The feature is being accounted for as a redemption under ASC 480.

We are accounting for our Series C preferred shares under the requirements of ASC 480 which establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. The carrying value of the Series C preferred shares is presented in as temporary equity and is increased by periodic accretions so that the carrying amount will equal the redemption amount at the estimated date that the Series C preferred shares will be converted into ordinary shares. These increases are affected through charges against additional paid-in capital, to the extent it is available, or accumulated deficit. For all issuances of Series C preferred shares, the difference between the amount invested by the holders of the Series C preferred shares, net of issuance costs and the initial fair value of warrants issued in connection with the Series C preferred shares (if applicable) and the liquidation value of the Series C preferred shares is recorded as accretion over the estimated life of the Series C preferred shares. The accretion is added to net loss to arrive at the net loss available to ordinary shareholders in the calculation of loss per ordinary share.

#### **Results of Operations**

# Comparison of Three Months Ended March 31, 2017 and 2018

The following table summarizes our results of operations for the three months ended March 31, 2017 and 2018, respectively:

	Th	Three Months Ended March 31,		
	2017	2018	Change	
Operating expenses:				
General and administrative	\$ 2,148,540	\$ 11,122,016	\$ 8,973,476	
Research and development	4,823,357	6,927,322	2,103,965	
Total operating expenses	6,971,897	18,049,338	11,077,441	
Loss from operations	(6,971,897)	(18,049,338)	(11,077,441)	
Other non-operating income (expense):				
Foreign currency gain	149,249	978,624	829,375	
Change in fair value of warrant liability		669,408	669,408	
Interest income	10,389	25,308	14,919	
Interest expense	( 8,126)	(27,355)	( 19,229)	
Net loss	\$(6,820,385)	\$ (16,403,353)	\$ (9,582,968)	

#### General and Administrative Expenses

General and administrative expenses were \$2.1 million for the three months ended March 31, 2017, compared to \$11.1 million for the three months ended March 31, 2018. The increase of \$9.0 million was primarily due to increases of \$5.8 million in payroll, \$3.3 million in stock-based compensation, \$0.1 million in consultant costs, \$0.1 million in legal and \$0.2 million in accounting fees, which was partially offset by decreases of \$0.4 million in rent and \$0.1 million in depreciation expenses.

# Research and Development Expenses

Research and development expenses for the three months ended March 31, 2017 were \$4.8 million, compared to \$6.9 million for the three months ended March 31, 2018. The increase of \$2.1 million was primarily due to an increase in costs of \$1.8 million related to preparation for production of our manufacturing facility. \$0.2 million in license fees and \$0.1 million in neurodegenerative research.

#### Foreign Currency Gain

Foreign currency gain was \$0.1 million for the three months ended March 31, 2017 compared to \$1.0 million for the three months ended March 31, 2018. The increase of \$0.8 million was primarily due to a weakening U.S. dollar against the pound sterling during the three months ended March 31, 2018.

Change in Fair Market Value of Warrant Liability

The change in fair market value of the warrant liability for the three months ended March 31, 2018 was due to the revaluation of warrants, which were issued to certain investors in September and November 2017, using the Black-Scholes valuation model at December 31, 2017 and March 31, 2018. As a result of the revaluation, there was a decrease of \$0.7 million in the fair market value of the warrant liability at March 31, 2018, which resulted in a gain being recorded for the three months ended March 31, 2018.

# Comparison of Years Ended December 31, 2016 and 2017

The following table summarizes our results of operations for the years ended December 31, 2016 and 2017, respectively:

		Year Ended December 31,	
	2016	2017	Change
Operating expenses:			
General and administrative	\$ 6,026,529	\$ 9,325,017	\$ 3,298,488
Research and development	14,037,918	22,359,712	8,321,794
Total operating expenses	20,064,447	31,684,729	11,620,282
Loss from operations	(20,064,447)	(31,684,729)	(11,620,282)
Other non-operating income (expense):			
Foreign currency gain	265,543	1,676,117	1,410,574
Convertible note inducement expense	_	(553,500)	(553,500)
Change in fair value of warrant liability	_	(465,633)	(465,633)
Interest income	32,068	26,073	(5,995)
Interest expense	(25,440)	(42,863)	(17,423)
Net loss	\$ (19,792,276)	\$ (31,044,535)	\$ (11,252,259)

# General and Administrative Expenses

General and administrative expenses were \$6.0 million for the year ended December 31, 2016, compared to \$9.3 million for the year ended December 31, 2017. The increase of \$3.3 million was primarily due to increases of \$0.8 million in payroll, \$0.5 million in legal, \$1.7 million in rent and \$0.3 million in depreciation expenses.

# Research and Development Expenses

Research and development expenses for the year ended December 31, 2016 were \$14.0 million, compared to \$22.4 million for the year ended December 31, 2017. The increase of \$8.4 million was primarily due to an increase in costs of \$2.5 million related to preparation for production of our manufacturing facility, \$0.9 million related costs of consultants, \$5.1 million of clinical trial costs related to our ophthalmology programs, \$0.8 million in payroll, \$1.0 million in neurodegenerative research, and \$0.4 million in share-based compensation which was partially offset by a decrease of \$0.6 million in acquired research and development related to an asset acquisition in 2016 and the receipt of a \$1.7 million research and development credit in the United Kingdom in 2017.

# Foreign Currency Gain

Foreign currency gain was \$0.3 million for the year ended December 31, 2016 compared to \$1.7 million for the year ended December 31, 2017. The increase of \$1.4 million was primarily due to a weakening U.S. dollar against the pound sterling in 2017.

# Convertible Note Inducement Expense

There was no convertible note inducement expense for the year ended December 31, 2016 compared to \$0.5 million for the year ended December 31, 2017. The increase of \$0.5 million was primarily due to the issuance of a warrant to purchase 231,898 Series C preferred shares in 2017 to a convertible noteholder as an inducement to convert the note into Series C preferred shares.

Change in Fair Market Value of Warrant Liability

There was no warrant liability for the year ended December 31, 2016, compared to \$0.5 million for the year ended December 31, 2017. The increase of \$0.5 million was primarily due to the revaluation of certain warrants, which were issued to certain investors in September and November 2017, using the Black-Scholes valuation model at December 31, 2017.

#### **Liquidity and Capital Resources**

Since our inception, we have incurred significant operating losses. We have not generated positive cash flows from operations, and there are no assurances that we will be successful in obtaining an adequate level of financing for the development and commercialization of its product candidates. These factors raise substantial doubt about our ability to continue as a going concern. We expect to incur significant expenses and operating losses for the foreseeable future as we advance the preclinical and clinical development of our product candidates. We expect that our research and development and general and administrative costs will increase in connection with conducting preclinical studies and clinical trials for our product candidates, building out internal capacity to have product manufactured to support preclinical studies and clinical trials, expanding our intellectual property portfolio, and providing general and administrative support for our operations. As a result, we will need additional capital to fund our operations, which we may obtain from additional equity or debt financings, collaborations, licensing arrangements, or other sources.

We are required to maintain a stand-by letter of credit as a security deposit under a certain lease with ARE, an entity that is under common control with an entity that is a minority shareholder of the Company and whose CEO is on our board of directors. See "Certain Relationships and Related Person Transactions." Our bank requires us to maintain restricted cash balances to serve as collateral for the letter of credit issued to the landlord by the bank. In connection with an amendment to one of the ARE leases in November 2017, one of the letters of credit in the amount of \$321,978 and the related restricted cash balance were released in December 2017. As of December 31, 2016 and 2017, the restricted cash balances for the ARE leases were invested in a commercial money market account. The restricted cash balance for the other ARE lease remains at \$123,376 through the end of the lease term in December 2021, plus three months. We had \$444,844 and \$123,376 of restricted cash included in long-term assets as of December 31, 2016 and 2017, respectively, and \$444,844 and \$123,376 of restricted cash included in long-term assets as of March 31, 2017 and 2018, respectively.

We do not currently have any approved products and have never generated any revenue from product sales. To date, we have financed our operations primarily through the sale of our Series C preferred shares and cash on hand.

#### Cash Flows

As of March 31, 2018, we had \$32.4 million of cash and cash equivalents.

The following table summarizes our sources and uses of cash for the period presented:

	Year E Deceml		Three Months Ended March 31,		
	2016	2017	2017	2018	
Net cash used in operating activities	\$ (14,367,952)	\$ (18,055,386)	\$ (6,395,338)	\$ (17,395,969)	
Net cash used in investing activities	(2,593,584)	(10,535,717)	(1,737,520)	(1,210,452)	
Net cash provided by financing activities	20,757,202	19,340,215	196,543	42,401,814	
Increase (decrease) in cash	\$ 3,795,666	\$ (9,250,888)	\$ (7,936,315)	\$ 23,795,393	

# **Operating Activities**

During the three months ended March 31, 2017, our cash used in operating activities of \$6.4 million was primarily due to our net loss of \$6.8 million as we incurred expenses associated with research activities on our clinical programs and research activities for our other product candidates and incurred general and administrative expenses. The loss included non-cash charges of \$0.9 million, which consisted of \$0.9 million of share-based compensation and depreciation of \$0.2 million, which was partially offset by a foreign currency gain of \$0.2 million. Additionally, current assets, consisting of prepaid expenses and other current assets, increased by \$0.5 million.

During the three months ended March 31, 2018, our cash used in operating activities of \$17.4 million was primarily due to our net loss of \$16.4 million as we incurred expenses associated with research activities on our clinical programs and research activities for our other product candidates and incurred general and administrative expenses. The loss included non-cash charges of \$3.2 million, which consisted of \$4.3 million of share-based compensation, depreciation of \$0.5 million and issuance of Series C preferred shares in connection with a license agreement of \$0.1 million, which was partially offset by a foreign currency gain of \$1.0 million and a change in the fair value of the warrant liability of \$0.7 million. Additionally, current liabilities, consisting of accounts payable, accrued expenses, deferred rent and due to affiliate, increased by \$4.2 million.

During the year ended December 31, 2016, our cash used in operating activities of \$14.4 million was primarily due to our net loss of \$19.8 million as we incurred expenses associated with research activities on our clinical programs and research activities for our other product candidates and incurred general and administrative expenses. The loss included non-cash charges of \$3.9 million, which consisted of \$2.8 million of share-based compensation, acquired research and development of \$0.6 million, issuance of shares for services of \$0.3 million and depreciation of \$0.2 million. Additionally, current liabilities, consisting of accounts payable, accrued expenses deferred rent and due to affiliate, increased by \$2.8 million, which was partially offset by increases in current assets, consisting of prepaid expenses and other current assets, in the amount of \$1.3 million.

During the year ended December 31, 2017, our cash used in operating activities of \$18.1 million was primarily due to our net loss of \$31.0 million as we incurred expenses associated with research activities on our clinical programs and research activities for our other product candidates and incurred general and administrative expenses. The loss included non-cash charges of \$3.0 million, which consisted of \$3.0 million of share-based compensation, change in fair value of warrant liability in the amount of \$0.5 million, convertible note inducement expense of \$0.5 million and depreciation of \$0.7 million, which was partially offset by a foreign currency gain of \$1.7 million. Additionally, current liabilities, consisting of accounts payable, accrued expenses

deferred rent and due to affiliate, increased by \$11.1 million, was partially offset by decreases in current assets, consisting of prepaid expenses and other current assets, in the amount of \$1.2 million.

**Investing Activities** 

Net cash used in investing activities for the three months ended March 31, 2017 and March 31, 2018 of \$1.7 million and \$1.2 million, respectively, consisted of purchases of property and equipment, primarily for our manufacturing facility.

Net cash used in investing activities for the year ended December 31, 2016 and December 31, 2017 of \$2.6 million and \$10.5 million, respectively, consisted of purchases of property and equipment, primarily for our manufacturing facility.

Financing Activities

Net cash provided by financing activities was \$0.2 million for the three months ended March 31, 2017, represented proceeds from the issuance of our Series C preferred shares.

Net cash provided by financing activities was \$42.4 million for the three months ended March 31, 2018, represented proceeds of \$43.8 million from the issuance of Series C preferred shares, which was partially offset by the payment of a note in the amount of \$1.4 million.

Net cash provided by financing activities was \$20.8 million for the year ended December 31, 2016, represented proceeds from the issuance of our Series C preferred shares.

Net cash provided by financing activities was \$19.3 million for the year ended December 31, 2017, represented proceeds of \$16.8 million from the issuance of Series C preferred shares and \$2.5 million from the issuance of a note payable.

#### **Funding Requirements**

Our operating expenses increased substantially in 2017 and are expected to increase substantially in the future in connection with our ongoing activities, particularly as we advance our clinical activities including scale-up of manufacturing processes and additional clinical trials. In addition, upon the closing of this offering, we expect to incur additional costs associated with operating as a public company.

Specifically, our expenses will increase as we:

- pursue the preclinical and clinical development of our product candidates;
- scale up our manufacturing processes and capabilities to support our preclinical studies and clinical trials of our product candidates;
- in-license or acquire the rights to other products, product candidates or technologies;
- maintain, expand and protect our intellectual property portfolio;
- hire additional personnel in research, manufacturing and regulatory and clinical development as well as management personnel; and
- expand our operational, financial and management systems and increase personnel, including personnel to support our operations as a
  public company.

Based on our planned use of the net proceeds of this offering and our current cash and cash equivalents, we estimate that such funds will be sufficient to enable us to fund our operating expenses and capital expenditure requirements through the third quarter of 2020. We have based these estimates on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect.

Because of the numerous risks and uncertainties associated with research, development and commercialization of gene therapies, it is difficult to estimate with certainty the amount of our working capital requirements. Our future funding requirements will depend on many factors, including:

- the progress, costs and results of our preclinical development and initial clinical trials for our gene therapy programs;
- · the progress, costs and results of our additional clinical, research and preclinical development programs in gene therapy;
- · the costs and timing of process development and manufacturing scale-up activities associated with our clinical programs;
- our ability to establish and maintain strategic collaborations, licensing or other agreements and the financial terms of such agreements;
- the scope, progress, results and costs of any product candidates that we may derive from our platform technology or any other product candidates that we may develop;
- · the extent to which we in-license or acquire rights to other products, product candidates or technologies; and
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights and defending against any intellectual property-related claims.

Until such time, if ever, that we can generate product revenue sufficient to achieve profitability, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaboration agreements, other third-party funding, strategic alliances, licensing arrangements and marketing and distribution arrangements.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a holder of ordinary shares. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through other third-party funding, collaboration agreements, strategic alliances, licensing arrangements or marketing and distribution arrangements, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market products or product candidates that we would otherwise prefer to develop and market ourselves.

#### **Contractual Obligations and Commitments**

The following is a summary of our significant contractual obligations as of December 31, 2017.

		Payments Due by Period				
		Less Than 1	More Than 1 Year and	More Than 3 years and Less Than	More Than	
Contractual Obligation	<u>Total</u>	<u>Year</u>	Less Than 3	<u>5</u>	5 years	
Operating lease obligation(1)	\$3,490,362	\$1,215,723	\$1,676,375	\$ 598,264	\$ —	
Capitalized, lease obligations(2)	70,304	34,410	35,894	_	_	
Notes payable(3)	1,527,147	1,527,147	_	_	_	
Total	\$5,087,813	\$2,777,280	\$1,712,269	\$ 598,264	\$	

<sup>(1)</sup> Represents the leases for office, laboratory, and manufacturing space in London, UK and New York, New York under non-cancelable operating leases that expire between July 2017 and December 2021. The lease for manufacturing space includes a 5-year option that, if exercised, would extend the expiration of that lease through February 2026. The obligation for such extension is not included in the above table.

(2) Represents future payments under capitalized leases for office equipment.

The contractual obligations table does not include any potential future payments we may be required to make under (1) our license agreements with UCL Business, plc, Brandeis University and other entities or (2) our sponsored research agreements with universities and commercial research organizations. These agreements may be terminated upon 30-90 days written notice and, therefore, the amounts to be paid by us are not fixed or determinable at this time.

# **Off-Balance Sheet Arrangements**

We have not entered into any off-balance sheet arrangements under applicable SEC rules and do not have any holdings in variable interest entities.

# **Quantitative and Qualitative Disclosures about Market Risk**

We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate sensitivities and foreign currency exchange rates. However, relative to foreign currency exposures as of December 31, 2017, a 10% unfavorable movement in foreign currency exchange rates would not expose us to a significant increase in net loss. We had cash and cash equivalents of \$17.5 million and \$8.5 million as of December 31, 2016 and 2017, respectively, which consist of bank deposits and money market funds. Such interest-earning instruments carry a degree of interest rate risk; however, historical fluctuations in interest income have not been significant for us. Other than accounts payable and accrued expenses incurred in the ordinary course of business, we had other debt outstanding of \$0 million as of December 31, 2016, and a note payable of \$1.4 million as of December 31, 2017.

# **Emerging Growth Company Status**

The Jumpstart Our Business Startups Act of 2012, or the JOBS Act, permits an "emerging growth company," which we are, to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have elected to take advantage of this extended transition period.

<sup>(3)</sup> Represents our note payable to ARE East-River Science Park LLC that bears interest at an annual rates of 5.0% and is due on December 31, 2018. The balance includes interest payment obligations.

#### BUSINESS

#### Overview

We are a vertically integrated, clinical stage gene therapy company with four ongoing clinical programs and a broad pipeline of preclinical and research programs. We have core capabilities in viral vector design and optimization and gene therapy manufacturing, as well as a potentially transformative gene regulation technology. Led by an experienced management team, we have taken a portfolio approach by licensing, acquiring and developing technologies that give us depth across both product candidates and indications. Though initially focusing on the eye, salivary gland and central nervous system, we intend to expand our focus in the future to develop additional gene therapy treatments for patients suffering from a range of serious diseases.

We operate a flexible and scalable viral vector manufacturing facility that we expect can supply our current clinical and preclinical programs through regulatory approval and, should they be approved, provide sufficient capacity for commercial production. Completed in early 2018 and designed to meet global regulatory requirements, including the current good manufacturing practices, or cGMP, required by the U.S. Food and Drug Administration, or FDA, our 29,000 square foot facility has two cell production suites, three independent viral vector production suites providing multiproduct and multi-viral vector manufacturing capabilities and an integrated, flexible fill-and-finish suite. In May 2018, we were granted a license to manufacture gene therapy product candidates in our cGMP compliant manufacturing facility by the UK Medicines and Healthcare products Regulatory Agency.

We have also established a comprehensive platform for the efficient clinical development of the next generation of gene therapies and manufacturing in accordance with cGMP. Our deep understanding of disease models informs our development of potency assays for the cGMP production of our product candidates, and our teams experienced in viral vector design and optimization work closely with our process development team to design viral vectors and develop proprietary production cell lines for efficient scaling of manufacturing processes.

We are also developing a potentially transformative technology to enable the use of small molecules to turn gene therapy product candidates on and off. The aim of this gene regulation platform is to convert gene therapy into a generalizable delivery mechanism for biologic drugs using a small molecule "switch" for temporal control. We believe the capacity for temporal control of gene therapy products has the potential to transform the gene therapy landscape by opening up new treatment possibilities.

# **Our Pipeline**

Our initial focus is on three distinct areas of unmet medical need: inherited retinal diseases, or IRDs, severe forms of xerostomia and neurodegenerative diseases. Utilizing our product development platform, we have assembled a pipeline of gene therapies to treat these serious diseases. Our criteria for selecting our initial product candidates included:

- · unmet medical need;
- high potential for meaningful clinical benefit;
- promising preclinical data using multiple animal models as well as human stem cell derived organoids;
- · compartmentalized anatomy of target tissue and the partially immune protected nature of target tissue; and
- understanding of the disease state from natural history studies and detailed long-term characterization of patients prior to entry into gene therapy treatment studies.

A summary of our product candidates is below. We retain worldwide development and commercialization rights to all of our product candidates.

Product	Indication	Development Stage		Stage	Status
Candidate	indication	Preclinical	Phase 1/2	Phase 3	Status
Ophthalmolog	y Programs				
AAV-CNGB3	Achromatopsia (CNGB3)	Orphan U.S. & EU RPDD; PRIME <sup>0,23</sup>	40		Phase 1/2 ongoing in UK <sup>(5)</sup>
AAV-CNGA3	Achromatopsia (CNGA3)				Phase 1/2 expected initiation in 2019
AAV-RPGR	X-linked RP (RPGR)	Orphan U.S. & EU Track Designation/	; Fast		Phase 1/2 ongoing
AAV-RPE65	RPE65-Deficiency (RPE65)	Orphan U.S. & EU RPDD <sup>(1,2,3)</sup>			Phase 1/2 ongoing
A006	Wet AMD (anti-VEGFR2)				First in man clinical trials expected 2019
Salivary Gland	d Programs				
AAV-AQP1	Xerostomia (hAQPI)	Orphan U.S. (1)			Phase 1 ongoing
AAV-AQP1	Sjogren's (hAQPI)				Phase 1/2 expected initiation in 2019
Neurodegener	ative Diseases Prog	ram			
AAV-UPF1	ALS (UPF1)				First in man clinical trials expected 2019

- Orphan drug designation by the FDA.
  Orphan drug designation by European Medicines Agency, or the EMA.
  Rare pediatric disease designation by Offices of Orphan Products Development and Pediatric Therapeutics of the FDA.
  Priority medicines, or PRIME, designation by the EMA.
  The IND for AAV-CNGB3 has not been opened yet because the FDA had a question about our device compatibility assay, placing the IND on clinical hold until the question has been satisfactorily answered. Fast Track designation by the FDA.

In addition to these clinical and preclinical programs, we have preclinical and research programs in other indications and novel molecular technologies that we aim to advance into clinical development, including:

- neovascular age related macular degeneration, or wet AMD use of a gene therapy product to deliver an antibody targeting the vascular endothelial growth factor receptor 2, or anti-VEGFR2, with the aim of blocking disease related vascular formation in the eye;
- geographic atrophy age related macular degeneration, or dry AMD use of gene therapy technology to introduce light sensitive molecules into rod photoreceptors in order to restore some aspects of vision lost in this disease;

- amyotrophic lateral sclerosis, or ALS—targeting dysregulation of neuronal RNA processing, which we believe may lead to the
  degeneration of motor neurons that occurs in ALS;
- · Alzheimer's disease—targeting endosomal trafficking, which is a central mechanism that we believe underlies Alzheimer's disease; and
- gene regulation—use of our proprietary RNA shape regulation cassette to switch gene therapy product candidates on and off with small molecules, potentially transforming gene therapy technology into a delivery mechanism for a broad array of biologic drugs.

# **Our Ophthalmology Programs**

Eye diseases are our first area of clinical focus and we aim to provide treatments with durable, long-term clinical benefit that will halt vision loss in patients. We currently have three ongoing Phase 1/2 clinical programs in IRDs, with an additional program expected to initiate a Phase 1/2 clinical trial in 2019. The targets of our three ongoing Phase 1/2 ophthalmology programs include achromatopsia, or ACHM, related to mutations in *CNGB3*, X-linked retinitis pigmentosa related to mutations in *RPGR*, or XLRP-RPGR, and inherited retinal dystrophy caused by mutations in *RPE65*, or *RPE65*-deficiency. We also have a product candidate that was manufactured and released for compassionate use under a specials license in the United Kingdom to treat patients with Leber congenital amaurosis 4, or LCA4, caused by mutations in *AIPL1*. For each of our Phase 1/2 clinical programs we have a prospectively designed natural history study ongoing, which includes the same endpoints as our corresponding gene therapy treatment trial. We believe use of these natural history studies differentiates our programs by providing patient populations to facilitate the efficient execution of our clinical trials and offering insight into the appropriate endpoints for regulatory approval of our gene therapy product candidates. In addition to these clinical programs in IRDs, we have preclinical programs that apply novel approaches to both wet and dry AMD.

The FDA and EMA have granted orphan drug designation to each product candidate in our ongoing clinical programs, including those treating mutations in *CNGB3*, *RPGR* and *RPE65*, as well our product candidate to treat mutations in *AIPL1*. The FDA has also granted rare pediatric disease designation for our clinical programs treating mutations in *RPE65* and *CNGB3* and Fast Track designation to our clinical program treating XLRP caused by mutations in *RPGR*. We have also received PRIME designation from the EMA for our clinical program treating mutations in *CNGB3*.

The deep scientific and clinical understanding of IRDs driving our approach to gene therapy development helps us to optimize our product candidates for each specific genetic mutation and phenotype. We develop our viral vectors by selecting and modifying proprietary cell specific promoters, selecting appropriate capsids for transfection of target cells and refining the vector for efficient production and scalable manufacturing. Not only does this allow us to synergistically target a portfolio of inherited eye conditions, we also believe it has potential to be applied to the development of gene therapies for other diseases.

Our longstanding relationships with leading institutions in retinal disease treatment, including the Moorfields Eye Hospital in London, the University of Michigan Kellogg Eye Center, Massachusetts Eye and Ear, the Medical College of Wisconsin & Froedtert Hospital and the Casey Eye Institute at the Oregon Health & Science University, provide us with access to experts whose guidance and insight informs our development strategy, as well potential patients for our clinical trials.

# **Our Salivary Gland Programs**

Our second area of clinical focus is xerostomia, a chronic and debilitating disorder of the salivary glands in which saliva production is impaired. Xerostomia may be caused by a number of different insults to the salivary

glands, including radiation therapy for head and neck cancer and certain autoimmune diseases. A Phase 1 clinical trial of our gene therapy product candidate, AAV-AQP1, is ongoing in patients who have survived cancer free for five or more years following treatment for head and neck cancer and are suffering from grade 2 or 3 radiation induced late xerostomia, or RIX. There are approximately 170,000 grade 2 or 3 RIX patients who have survived two or more years after radiation treatment for head and neck cancer in the United States, with approximately 10,000 new cases each year. We also intend to initiate a Phase 1/2 clinical trial of AAV-AQP1 for the treatment of patients with chronic xerostomia caused by Sjogren's syndrome, an autoimmune disease affecting more than two million people in the United States.

The FDA has granted orphan drug designation to AAV-AQP1.

#### **Our Neurodegenerative Disease Programs**

Neurodegenerative diseases are our third area of focus. Our first target indication is ALS and we expect to file an investigational new drug application, or IND, for our first neurodegenerative disease product candidate in 2019. We believe our approach to treating ALS patients is differentiated because, rather than targeting a specific genetic defect that defines a small subset of ALS patients, we aim to target the underlying cell biology driving motor neuron death in ALS, potentially enabling us to treat a broader patient population that includes both sporadic and inherited forms of the disease. Increasing evidence suggests a critical role of RNA metabolism in neuronal cells, in particular in motor neurons that are specifically affected in ALS. We believe that dysregulation of neuronal RNA processes results in the degeneration of motor neurons that leads to ALS. Using our viral vector product candidate, AAV-UPF1, we target the central quality control system regulating RNA in motor neurons with the aim of enhancing motor neuron survival in ALS patients.

We have an Alzheimer's disease program that is likewise directed towards the underlying cell biology of the disease, in this case endosomal trafficking, a mechanism cells use to cycle proteins to the cell surface. Over the past decade, evidence has emerged supporting endosomal trafficking dysfunction in neurons as a central process in the early etiology of Alzheimer's disease. In particular, a master regulator of trafficking out of the endosomes called retromer has been implicated. We are in the process of identifying what we believe to be the optimal approach to restoring normal endosomal function to the neurons that are the first to be affected in Alzheimer's. In parallel, we are developing and validating biomarkers of endosomal dysfunction and pre-symptomatic Alzheimer's disease. We believe this approach may also provide a framework for treating certain forms of Parkinson's disease that are also associated with endosomal dysfunction.

#### **Our Strengths**

In addition to our four ongoing clinical programs, we have a broad pipeline of preclinical programs, core capabilities in viral vector design and optimization, gene therapy manufacturing and a potentially transformative gene regulation technology. Utilizing the following key strengths, we aim to develop, commercialize and expand our portfolio of product candidates.

- **Deep Expertise in Gene Therapy Development:** We believe our expertise in viral vector design, optimization and process development allows us to efficiently advance gene therapy products candidates from preclinical development to cGMP manufacturing and clinical development through commercialization.
- **Potentially Transformative Gene Regulation Technology Platform:** We are developing proprietary technology to enable innovative gene therapy treatments whose expression can be turned on and off with an easily administered small molecule. We believe the capacity for temporal control of gene therapy products has the potential to transform the gene therapy landscape by opening up new treatment possibilities.

- Manufacturing Capabilities and Capacity: We have a flexible and scalable cGMP manufacturing facility and production process, which we expect can supply all of our current clinical and preclinical programs through regulatory approval and, should they be approved, provide sufficient capacity for their commercial production.
- **Robust and Diverse Clinical and Preclinical Pipeline:** Applying our portfolio approach to gene therapy product development, our initial focus is on treatments for IRDs, salivary glands disorders and neurodegenerative diseases with potential for accelerated approval and has produced four ongoing clinical programs and multiple preclinical development programs.
- **Relationships with Leading Institutions:** Our longstanding relationships with leading institutions and experts provides us with guidance on development strategy and access to potential patients for our clinical trials.
- Natural History Study Data: We sponsor ongoing prospective long-term natural history studies in IRDs that facilitate our ability to
  efficiently enroll our treatment studies, potentially reducing clinical trial timelines and providing insight into the appropriate endpoints
  for regulatory approval.

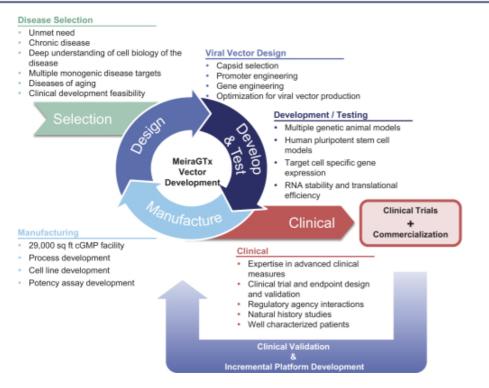
# **Our Strategy**

Our goal is to develop and commercialize innovative gene therapy products to treat serious disorders and broaden the scope of indications that may be treatable by our gene therapies. Our strategy to achieve this goal is to:

- successfully complete clinical development, obtain regulatory approval and commercialize our pipeline of gene therapy product candidates to treat disorders of the eye and salivary gland;
- · continue to advance the development of our pipeline of product candidates for the treatment of neurodegenerative disorders;
- utilize our viral vector design and optimization capabilities to identify and develop new gene therapies for other serious diseases;
- advance the development of our potentially transformative proprietary technology for regulating the activity of gene therapy products using small molecules and initiate clinical trials of new product candidates; and
- evaluate strategic collaborations with other biotechnology and pharmaceutical companies to leverage our capabilities, manufacturing capacity and proprietary gene regulation technology.

The figure below depicts the steps in our product engine, including disease selection, design, development/testing, clinical and manufacturing:

# MeiraGTx Product Engine



#### **Gene Therapy Overview**

Gene therapy uses a delivery vehicle, referred to as a vector, to insert a functionally active gene into cells in the body. The gene encodes a therapeutic protein that may block disease pathways or may enhance a deficient pathway. Gene therapy has been studied for over 50 years, with a variety of different viral vectors employed to deliver therapeutic genes. Since the first clinical study of therapeutic gene transfer in humans in 1990, more than 2,300 gene therapy studies covering a broad range of disease targets have been initiated. Recently, the first gene therapies have received regulatory approval, including approval by the FDA of Luxturna for an ophthalmology condition, resulting in a growing acceptance of gene therapy technology as a potentially safe and effective therapeutic approach.

Our current programs use the adeno-associated virus, or AAV, as the vector for delivering gene sequences into a patient's cells. The key components of an AAV vector include: (i) the capsid, or the outer viral protein shell that encloses the target DNA, which is responsible for binding to the cell surface and allowing the therapeutic gene that it is carrying to enter the cell; (ii) the therapeutic gene, or transgene, that encodes the therapeutic protein; and (iii) the promoter, or the DNA sequence that drives the expression of the transgene. AAV is a good vector for gene therapy delivery because of its relative safety and broad applicability. AAV is less immunogenic, or less prone to causing an immune reaction, than previous generations of gene therapy vectors, such as adenoviral vectors and AAV does not readily integrate into the genome of the target cell, reducing the potential for oncogenesis, or the induction of cancer. AAV vectors can transfer a therapeutic gene into, or transduce, numerous cell types. Slight differences in capsid proteins can modulate the efficiency with which

different capsids deliver genes to different cells, thus allowing different AAV capsids to be selected to most effectively target particular cell types.

The therapeutic gene sequence that enters the targeted cell includes both the protein coding region and an engineered promoter sequence that is used to drive functional gene expression. These engineered promoters may be designed to drive different levels of gene expression or to limit gene expression to specific cell types. Additional aspects of the transgene sequence may be engineered for optimal gene expression, such as codon usage and synthetic introns, which may enhance levels of therapeutic protein expression.

Gene therapy can be used to address monogenic diseases, which result mutations in a single gene in a patient's genome. In such cases, the viral vector is used to deliver a normal copy of the gene to the cells that are defective due to the lack of the gene function. The normal gene then drives production of the missing protein and offers a therapeutic benefit in patients with the disease. This gene replacement approach underlies all of our clinical IRD programs.

Rather than replacing a gene that is defective or missing in a monogenic disease, gene therapy can also provide a therapeutic impact by adding a particular new gene function to cells and thereby change cell behavior and function. This is the aim of our salivary gland programs, where our treatment is designed to promote water to flow through otherwise impermeable cells in damaged salivary glands and increase saliva flow into the mouth. Additionally, gene therapy may be used to deliver a therapeutic protein that may block a disease pathway or enhance a deficient cellular pathway in multifactorial diseases such as wet AMD and neurodegenerative diseases, including ALS and Alzheimer's disease.

Importantly, AAV vectors enable targeting of therapeutic genes to non-dividing cells, in which they are thought to remain for the rest of the cell's life. This means that a single treatment may offer patients a durable effect and long term benefit. The specific cells of the eye, salivary gland and the neurons that we target in our current gene therapy programs are largely non-dividing cells and preclinical evidence has shown that they can be effectively targeted by the specific AAV capsids that we use, enabling us to potentially achieve a durable impact on each of the diseases that we treat.

#### **Our Ophthalmology Programs**

#### **Overview and Strategy**

We currently have three ongoing Phase 1/2 clinical programs targeting IRDs, including ACHM related to mutations in *CNGB*3, XLRP-RPGR and *RPE65*-deficiency, with an additional program expected to enter a Phase 1/2 clinical trial in 2019 in patients with ACHM related to mutations in *CNGA*3. We also have a product candidate that was manufactured and released for compassionate use under a specials license in the UK to treat LCA4 patients. We chose diseases of the eye as our first area of clinical focus because we believe the eye is ideally suited for gene therapy for the following reasons.

- The eye is easily accessible and has highly compartmentalized anatomy, which allows for accurate delivery of vectors to specific tissues using direct visualization and microsurgical techniques.
- The structure of the eye allows for efficient delivery to specific cell subtypes with small volumes of vector, making the dose per patient much lower than for systemic treatment.
- Anatomical barriers and unique structure of the eye make the immune response to the intraocular administration of vectors more attenuated than systemic administration.
- Largely non-dividing cell populations in the eye make good targets for potentially stable, long-term gene delivery and expression.

• The retina, a structure in the back of the eye, is visible and there are many well validated structural and functional readouts allowing the detailed assessment of the therapeutic impact of the gene therapy treatment.

Our strategy for developing gene therapies targeting eye diseases is to begin with a number of monogenic IRDs that are good candidates for gene replacement therapies and expand to more common eye diseases over time. We have taken a portfolio approach to the development of IRDs because, while some of these genetic defects are rare, IRDs as a class are one of the most common causes of blindness in working age adults and there are multiple synergies at the clinical, regulatory and commercial levels between many of these diseases caused by different gene mutations.

Two of our clinical-stage product candidates are targeting IRD indications in achromatopsia caused by mutations in the *CNGB3* gene and inherited retinal dystrophy caused by mutations in the *RPE65* gene. The primary defect in these particular genetic disorders is the absence of function of one of the two different types of photoreceptors that constitute the light sensing part of the retina, rods or cones. In achromatopsia, the cones completely lack function, while in *RPE65*-deficiency it is the rods that lack function. In these indications, we anticipate that restoring a normal copy of the mutant gene to the retina of patients with these genetic disorders may restore function to the particular type of photoreceptor that is defective in each of these indications. Although cone photoreceptors are generally preserved during childhood in *RPE65*-deficient patients, the lack of healthy active rods eventually affects the cones that they support and over time both rods and cones die, the retina degenerates and *RPE65*-deficient patients become totally blind.

We also have a clinical-stage product candidate for XLRP-RPGR, in which all photoreceptors, both rods and cones, function poorly, leading to degeneration of the retina and total blindness. We have used data and learnings from our *RPE65* studies to inform the design and techniques used in our XLRP-RPGR program. The aim of our XLRP-RPGR treatment is to slow the degeneration of the retina, which we measure using validated surrogate structural endpoints and changes in the detailed structural maps of these patients' retinas over time.

In order to expand our gene therapy pipeline for retinal diseases, we are also developing treatments for certain multifactorial eye diseases, which are diseases caused by multiple genetic or environmental factors. We have a preclinical program using an anti-VEGFR2 antibody targeting wet AMD and we anticipate filing an IND for this program by the end of 2019. We are also working to integrate our gene regulation technology with our wet AMD program. Our ultimate aim is to activate the anti-VEGFR2 antibody gene that we have installed in the eye with a small molecule applied topically in an eye drop. This could potentially allow for intermittent dosing of the antibody using an eye drop rather than injection. Additionally, we are developing a novel approach to treat advanced dry AMD patients who have lost central vision through our innovative "rod-to-cone" technology. By genetically engineering rods with molecules that will improve their speed of response to light, we aim to effectively transform a patch of rod photoreceptors in the outer part of the retina to behave more like cone photoreceptors, thus improving vision.

We intend to leverage our platform to take advantage of the many synergies across our ophthalmology programs, including identification, diagnosis and characterization of patients, specialized surgical techniques, clinical and regulatory process, vector production and cGMP manufacturing, as well as commercial synergies, if these product candidates are approved by the FDA and other regulatory authorities.

# Our Competitive Advantage: Natural History Studies, Relationships with Leading Institutions and Our cGMP Manufacturing Facility

IRDs as a class are the most common cause of blindness in the working age population worldwide and a leading cause of impaired vision in children in developed countries. There are approximately 200,000 people in each of the United States and European Union affected by IRDs. However, IRDs may be caused by mutations in over 200 identified genes, and in many cases each genetically defined IRD may be a small patient population. Meaningful clinical trials for these sorts of rare indications are especially challenging because they require access

to sufficient patients and baseline data on each patient in order to secure clear indicators of efficacy as a result of intervention. We seek to address this problem by sponsoring prospectively designed natural history studies in each of the indications that we are treating in our Phase 1/2 trials.

The lead investigator for the natural history studies is Michel Michaelides, Professor of Ophthalmology at Moorfields Eye Hospital in London. For each of the natural history studies, baseline assessments are made upon enrollment, with follow up assessments at six month intervals for two years and annual assessments for up to an additional three years. A broad range of assessments are used, including functional tests, retinal imaging and electrophysiological assessments. The same assessments used for each natural history study are used in our corresponding clinical trial targeting the same indication, allowing us to compare the impact of our product candidates on the progression of these diseases on a population, as well as individual patient basis.

We expect the natural history studies will enhance our understanding of disease progression for each indication we are targeting and allow us to identify optimal windows for intervention, provide specific functional and structural parameters to quantify treatment effects and define clinical endpoints. These studies also provide us with a source of potential patients for our treatment studies and have facilitated efficient enrollment of these studies. These patients are not only genotyped, but have up to five years of detailed functional and structural assessment data prior to enrollment into an appropriate treatment study.

We also have longstanding active relationships and clinical site agreements with leading institutions in retinal disorder treatments, including Moorfields Eye Hospital in London, the University of Michigan Kellogg Eye Center, Massachusetts Eye and Ear, the Medical College of Wisconsin & Froedtert Hospital and the Casey Eye Institute at the Oregon Health & Science University. Our relationships with these institutions, in most cases, precede the date on which we entered into a clinical site agreement with the applicable institution. Professor Robin Ali, Ph.D., our Head of Preclinical Ophthalmology and one of our founders, is Professor of Human Molecular Genetics at UCL Institute of Ophthalmology and Theme Leader for Gene Therapy at NIHR Biomedical Research Centre for Ophthalmology, Moorfields Eye Hospital in London, and a Visiting Professor at the University of Michigan Kellogg Eye Center. These institutions are among the premier treatment centers for the indications that we are pursuing and provide us with access to potential patients for our clinical trials and experts in IRDs who offer strategic guidance and expertise for our development strategy. These institutions provide services with respect to our preclinical and clinical studies. For example, our AAV-CNBG3 clinical trial is being conducted at Moorfields Eye Hospital in London, and surgeries for our AAV-RPE65 clinical trial have been performed there and at University of Michigan Kellogg Eye Center. Participants enrolled at the University of Michigan Kellogg Eye Center for our *RPE65*-deficiency natural history study travel to the Medical College of Wisconsin & Froedtert Hospital for adaptive optic assessments. The Casey Eye Institute at the Oregon Health & Science University provides certain reading center and other clinical services with respect to our clinical trials. University of Michigan Kellogg Eye Center, Medical College of Wisconsin & Froedert Hospital and Massachusetts Eye and Ear each provide services in relation to our natural history study for

We believe our flexible and scalable cGMP compliant manufacturing facility has sufficient capacity to support the development needs for our current clinical and preclinical ophthalmology programs, and commercial needs, if our product candidates are approved by the FDA and other regulatory authorities.

# Achromatopsia

Disease Background and Market Opportunity

Achromatopsia, or ACHM, is an IRD that specifically prevents cone photoreceptors from functioning. ACHM patients are legally blind from birth and usually suffer from severely reduced visual acuity of 20/200 or worse, a disabling sensitivity to light, or photoaversion, total color blindness and involuntary back and forth eye movements, or nystagmus.

Cones and rods are the two kinds of photoreceptors in the human eye. Photoreceptors are light-sensitive cells that absorb light and convert it into an electrical signal that is transmitted to the brain for the perception of

light, or vision. Rods can detect very low levels of light and are quickly inactivated in higher light levels, enabling vision in dim light. Cones, on the other hand, remain active in high light levels and support daytime vision and the perception of color. Even though only 5% of the photoreceptors in the eye are cones, they are concentrated in the central part of the retina, the macula, where they are tightly packed, thus enabling high-acuity daytime vision. The highest cone density is in the centermost spot of the macula, called the fovea. Since cones are essential for central visual acuity, color vision, and most daily visual activities, ACHM patients suffer significant vision loss due to the complete lack of cone function.

ACHM occurs in approximately one in 30,000 people in the United States. To date, mutations of any one of six genes encoding components of the light sensing machinery of cone photoreceptors have been identified as causing ACHM. The *CNGB3* and *CNGA3* genes are the two most common of these genes, together accounting for up to 92% of ACHM cases, with *CNGB3* slightly more common than *CNGA3* in most geographic territories. Together, the proteins encoded by the *CNGB3* and *CNGA3* genes make up the cone-specific cyclic nucleotide gated, or CNG, channel, which is essential for cones to produce an electrical signal in response to light. Mutations in either of these genes prevent the formation of the CNG channel.

There are estimated to be approximately 12,000 patients with ACHM caused by mutations in *CNGB3* in the United States, Japan and Germany, France, Spain, Italy and the United Kingdom, or the EU5, with about 25% of those patients being under the age of 18 and approximately 125 new cases being diagnosed annually. We believe the availability of a therapeutic option may increase patient identification and the estimated prevalence of ACHM

### Our Gene Therapy Program

We have designed specifically optimized gene therapy viral vector candidates to treat ACHM caused by mutations in each of *CNGB3* and *CNGA3*, with which we aim to address the majority of patients suffering from ACHM. Our product candidates are delivered via subretinal injection covering the central macula region of the eye, where most of the cones in the retina are located.

ACHM is predominantly a stationary disease, which means that ACHM patients' retinas contain non-functioning cones that survive intact for many decades. This is in contrast to many IRDs in which the entire retina slowly degenerates over a patient's life. This extended survival of cones with their potential for light sensitivity presents a wide window of opportunity to introduce a normal copy of the mutated gene via a gene therapy product candidate and thereby restore cone function. While the stationary nature of ACHM means that cones remain present for decades, the functional connections between active cones and the visual cortex in the brain are thought to become fixed in teenage years. Therefore, we believe that younger individuals are likely to benefit most from gene therapy treatment for ACHM because of their greater visual plasticity. Another debilitating symptom of ACHM, which lasts throughout life, is photoaversion. A disabling and ubiquitous symptom of ACHM, photoaversion is the avoidance of light due to discomfort in the presence of levels of light equivalent to a normally lit room or daylight. ACHM patients often avoid light and wear dark glasses, which further diminishes their already very poor vision. We believe it is possible that restoration of cone function in adult patients might have an impact on photoaversion even if brain plasticity is limited.

We believe that gene therapy treatment for ACHM in which we aim to restore cone function via a gene replacement strategy may offer benefits across a range of ages, which we aim to define in our clinical development programs.

## ACHM Caused By Mutations in CNGB3

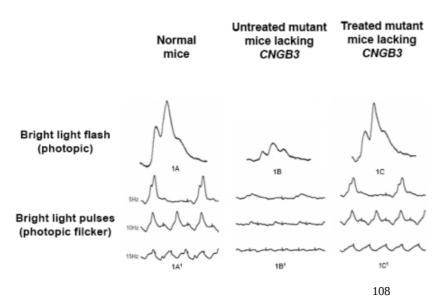
With our collaborators at the University College of London's Institute of Ophthalmology, or UCL IO, led by Professor Robin Ali, we have developed a product candidate to treat ACHM caused by mutations in the *CNGB3* gene. Mutations in the *CNGB3* gene prevent cone photoreceptors from functioning because *CNGB3*'s gene product is integral to the formation of a specific membrane channel that enables cones' electrical response to light. *CNGB3* is a gene exclusively expressed in cones and our aim is to replace the absent function of the mutant *CNGB3* gene with a normal copy of the gene in cones of IRD patients and thereby restore cone function.

In order to drive expression of the functional gene specifically in cones and not in other cells of the retina, we use the cone specific human cone arrestin, or CAR, promoter to drive the expression of a codon optimized *CNGB3* cDNA. Codon optimization improves protein expression by increasing translation efficiency. To transfect cone photoreceptors, we use the AAV8 capsid, which enables the efficient delivery of the *CNGB3* gene cargo to those photoreceptors. As the vast majority of the cones in the eye are located centrally and concentrated in the macula, we treat this central region of the retina through subretinal injection to deliver the viral vector product candidate to the photoreceptors in which its activity is required.

Preclinical studies in mice lacking the *Cngb3* gene were carried out by our collaborators at UCL IO and led by Professor Robin Ali in 2010 and 2011 and the data was published in *Human Molecular Genetics* in 2011. In these studies, it was observed that delivery of our *CNGB3* product candidate, AAV-CNGB3, via subretinal injection at doses between 6E<sup>9</sup> and 8E<sup>9</sup> viral genomes per eye, or vg/eye, was associated with a restoration of cone function to near normal levels.

In one of these studies, retinal response to light was measured in three groups of mice: Cngb3 mutant mice treated with AAV-CNGB3, untreated Cngb3 mutant mice and normal mice. Mice were treated with AAV-CNGB3 vector dosed at  $2E^{12}$  vg/mL ( $8E^9$  vg/eye) via subretinal injection. One eye was treated per mouse. Vector was administered when mice were 30 days old, and electrical responses, or ERGs, of the retina were measured 90 days following administration of the vector.

Figure 1 shows representative ERG responses of the retina to different light stimuli: a single flash of bright light (1A; 1B; 1C) and repeated pulses, or flickers, of bright light at different frequencies to assess the refresh rate of the photoreceptors (1A'; 1B'; 1C'). Retinas from three different groups of mice were tested: retinas of normal mice (Figure 1A), retinas of mutant mice lacking the *Cngb3* gene (Figure 1B) and retinas of mutant mice lacking the *Cngb3* gene, but treated with AAV-CNGB3 (Figure 1C). It was observed that the response to a bright light pulse was largely absent in the retinas of *Cngb3* mutant mice, as this response is largely mediated by the cones and is therefore severely impacted by the *Cngb3* mutation (Figure 1B). It was also observed that treatment of *Cngb3* mutant mice with AAV-CNGB3 was associated with a high-degree of restored cone function in these mutant mouse retinas in response to a single flash of bright light (Figure 1C). In addition, we tested the response of cones to rapid flickers of bright light (Figure 1A') because only cones can register multiple sequential signals from rapid flickers. It was observed that registering rapid flickers was also impacted by the *Cngb3* mutantion (Figure 1B') and the cone flicker response was nearly completely restored in the retinas of *Cngb3* mutant mice following treatment with AAV-CNGB3 (Figure 1C').



**Figure 1.** Electrical responses of the retina reacting to two different light stimuli: a single flash of bright light and repeat pulses of bright light at increasing frequency, or flickers.

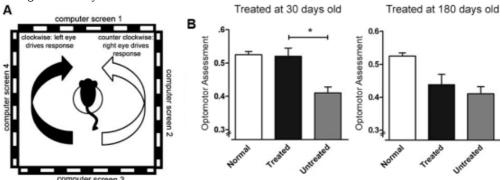
**Figure 1A** and **1A'**. The electrical responses of the retina from a normal mouse reacting to a flash of bright light and flickers.

**Figure 1B and 1B'.** The electrical responses of the retina from a mutant mouse lacking *Cngb3* reacting to a flash of bright light and flickers.

**Figure 1C and 1C'.** The electrical responses of the retina from a mutant mouse lacking *Cngb3* treated with AAV-CNGB3 reacting to a flash of bright light and flickers. Treatment with AAV-CNGB3 was associated with a high degree of restoration of cone function, with the electrical response to a bright flash of light and rapid flickers nearly matching the response observed in the normal mouse retina.

In another one of the preclinical studies carried out by our collaborators at UCL IO, it was assessed whether functional improvement at the retinal level of *Cngb3* mutant mice was impacted by the age of the mice at the time treatment with the gene therapy product candidate. In this study, *Cngb3*-mutant mice were treated with AAV-CNGB3 at 30 days old, the P30 group, or 180 days old, the P180 group. One eye was treated in each mouse via subretinal injection dosed at 2E12 vg/mL (8E9 vg/eye). Optomotor measurements were taken 60 days after treatment of the P30 group of the *Cngb3* mutant mice treated with AAV-CNGB3 (n=11), untreated *Cngb3* mutant mice (n=11) and normal, age-matched untreated mice (n=5). Optomotor measurements were also taken 60 days after the treatment of the P180 group of the *Cngb3* mutant mice treated with AAV-CNGB3 (n=6), untreated *Cngb3* mutant mice (n=6) and normal, age-matched untreated mice (n=5). Optomoter assessments were made by placing each mouse on a pedestal located in the center of four inward facing computer screens, that projected a rotating image. The head-tracking responses of each mouse was observed using an overhead infrared video camera. Visual acuity was measured by involuntary reflex head-tracking responses driven by the left (clockwise rotations, black arrow) and right (counter-clockwise rotations, white arrow) eyes, respectively (Figure 2A).

Figure 2B is a graph comparing the visual acuity as measured by the average optomotor assessment of the normal eyes, eyes from *Cngb3* mutant mice treated with AAV-CNGB3 and eyes from *Cngb3*-mutant mice that were untreated. It was observed that *Cngb3* mutant mice had a significantly lower visual acuity than normal mice. However, after treatment with AAV-CNGB3, visual acuity in the *Cngb3* mutant mice eyes treated at 30 days old was observed to be restored to a similar level as that observed in normal mice. In contrast, no significant difference in visual acuity between the treated and untreated eyes was observed when treatment was given at 180 days old. Data from this study suggests that treatment received at an older age is less capable of restoring visual acuity.



**Figure 2A.** Depiction of how optomotor assessments were taken. Each mouse was placed on a pedestal located in the center of four inward facing screens and was observed by an overhead infrared video camera. The assessments were made 60 days following treatment of the *Cngb3* mutant mice with AAV-CNGB3 at 30 days old and 180 days old.

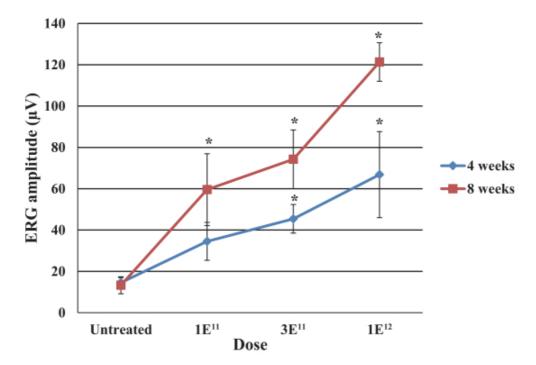
**Figure 2B.** Graph showing averaged optomotor assessment of each group. Visual acuity, as measured by the optomotor assessment, was observed to be restored to normal levels in the mouse treated at 30 days old (left panel) but not in the mouse treated at 180 days old (right panel).

Between October 2016 and December 2016, we carried out a dose-ranging preclinical study at UCL IO to determine the efficacy of different doses of AAV-CNGB3 in rescuing cone response to a single pulse of bright light in *Cngb3* mutant mice as measured by electrical responses across the retina, or ERG. The study was conducted to support a planned Phase 1/2 clinical trial in patients with *CNGB3* mutations following the FDA's request for additional rescue data at a range of different doses. While long-term functional rescue was observed in prior tests, there was no dosage titration tested in those studies. The data from this study has not been published.

We assessed cone-mediated ERG responses in *Cngb3* mutant mice at three doses and compared these responses to baseline recordings of untreated eyes at two different time-points following treatment. *Cngb3* mutant mice were administered AAV-CNGB3 via subretinal injection of 4uL of vector at each dose. Mice were treated at four weeks of age and ERG responses were measured in these mice at four weeks and eight weeks following treatment. Three eyes were treated at each of the three doses, and three eyes were untreated. The reviewer analyzing the ERG traces was masked to which eye received treatment.

Figure 3 shows the photopic ERG amplitudes measured to assess cone photoreceptor function in *Cngb3* mutant mice treated with AAV-CNGB3 at 1E<sup>11</sup> vg/mL (4E<sup>8</sup> vg/eye; n=3), 3E<sup>11</sup> vg/mL (1.2E<sup>9</sup> vg/eye; n=3) and 1E<sup>12</sup> vg/mL (4E<sup>9</sup> vg/eye; n=3), and untreated eyes (n=3) at four and eight weeks post administration. A photopic ERG is the electrical response of the retina corresponding to cone electrical activity following a single pulse of bright light (single ERG recordings are shown in Figure 1). The higher the ERG amplitude, the greater the response of the retina to bright light. These data show a statistically significant increase in cone ERG responses for all three doses of AAV-CNGB3 and for both time-points following vector administration except for low dose at four weeks post injection (p=0.051). These data indicate that AAV-CNGB3 is associated with the rescue of the cone electrical response in the retina of *Cngb3* mutant mice in a dose-responsive fashion. While initial responses were observed in mice four weeks after subretinal injection of the vector, at all three doses significantly stronger ERG responses were observed eight weeks after vector administration, with the maximum ERG response observed at the highest dose eight weeks after administration.

In this study, a dose response in ERG amplitudes from treated eyes was observed, suggesting that increasing amounts of AAV-CNGB3 is associated with greater rescue of responses in *Cngb3* mutant mice. The three doses tested in this study are the same as those doses administered in our AAV-CNGB3 Phase 1/2 clinical trial on a vg/mL of viral vector titer basis.



**Figure 3.** Graph of averaged photopic ERG amplitudes at four and eight week time-points post administration of AAV-CNGB in *Cngb3* mutant mice treated at four weeks of age. The blue line indicates the electrical response amplitudes observed following administration of different doses of AAV-CNGB3 measured at four weeks after treatment. The red line shows the increased level of electrical response observed in the same mice treated with AAV-CNGB3 four weeks later, at eight weeks following treatment. This is compared to the ERG response in untreated eyes, which remained unchanged at both time points.

During 2016, we conducted three preclinical toxicology studies of AAV-CNGB3 at UCL IO. We conducted a nine month study in normal mice in which four eyes were dosed with saline as a control, nine eyes were dosed at  $2E^9$  vg/eye, and nine eyes were dosed at  $4E^9$  vg/eye, with a toxicology assessment at one, three, six and nine months post-administration. We also conducted an eight week study in normal mice, in which 15 mice were dosed with saline as a control, 15 mice were dosed at  $2E^9$  vg/eye, and 15 mice were dosed at  $4E^9$  vg/eye, providing five mice from each group for studying local and systemic effects at each time-point of one, four and eight weeks after treatment. We also conducted an eight week rabbit study in which the right eyes of nine animals were dosed at  $2E^9$  vg/eye, providing three animals from each dose group for studying local and systemic effects at each time-point of one, four and eight weeks after treatment. Biodistribution was examined in the eight week mouse and rabbit studies. No harmful effects on the retina or systemically were observed at the time-points listed after treatment. The data from these studies have not been published. We used these data to support our clinical trial application, or CTA, and IND for treatment of patients with ACHM related to *CNGB3* mutations with AAV-CNGB3.

## Clinical Development of AAV-CNGB3

We have an ongoing natural history study in ACHM including over 90 patients that allows us to collect structural and functional data for up to five years on prospectively defined endpoints, including functional tests (visual acuity, contrast sensitivity, mobility maze and photoaversion assessments), retinal imaging (color fundus

photography, fundus autofluoresence imaging, spectral domain optical coherence tomography and visual field testing) and electrophysiological assessments. The study center is the Moorfields Eye Hospital in London. We believe access to these ACHM patients has enabled us to efficiently enroll the most appropriate patients into our *CNGB3* Phase 1/2 clinical trial. We intend to present this natural history data to regulatory agencies for discussion of our pivotal trial design and path to regulatory approval. In addition to giving us access to patients and potentially accelerated enrollment in our treatment studies, we believe the prospective natural history data on each treated patient allow us to gather robust data from our Phase 1/2 clinical trial in a condensed timeframe.

We are conducting a Phase 1/2 clinical trial of AAV-CNGB3 in both adult and pediatric patients. In the dose escalation phase of the trial, up to 18 adult patients (18 years or older) may be administered one of three different doses of vector in dose escalating cohorts of three to six patients at a time. We have treated patients in all three dose cohorts. We have also treated one pediatric patient in the expansion cohort of the trial. We will close out this trial six months after the last pediatric patient has been treated. Six months following treatment, each patient moves onto a long term follow up study in which they are followed for safety and indication of benefit for an additional four and a half years.

The primary endpoint of this open-label, dose-escalation clinical trial is the safety of a one-time subretinal administration of AAV-CNGB3 in patients with ACHM caused by *CNGB3* mutations. Secondary endpoints include the outcomes of a range of functional assessments and detailed structural analysis of the retina, including imaging of individual photoreceptors.

This trial is open in the United Kingdom under our CTA. We have treated 10 adult patients at the Moorfields Eye Hospital in London, including three patients at the highest proposed dose, and one pediatric patient.

We submitted our IND for AAV-CNGB3 to the FDA in the fourth quarter of 2017. The IND has not yet been opened because we received a question from the FDA regarding our injection device compatibility assay, thus putting the IND on clinical hold until we have satisfactorily answered the FDA's question and the clinical hold is lifted by the FDA. In the device compatibility assay the FDA noted a disparity between the target titer for the intended low dose dilution and the actual titer obtained on polymerase chain reaction, or PCR, analysis. The FDA requested clarification on whether this was an imprecise dilution scheme for the low dose or a PCR assay issue. We submitted a response to the FDA on May 2, 2018 providing data that identified the issue as a PCR assay artifact and also showing data that we believe supports that this has now been addressed. Although we are unable to extend the ongoing study to sites in the United States until the clinical hold is lifted, we continue to treat patients in the UK under our CTA.

In this trial, AAV-CNGB3 viral vector is delivered via subretinal injection of up to 0.5 mL targeting the central region of the retina, including the macula and fovea, where most of the cones are located. One eye is treated in each patient, which is the eye assessed to be the worst eye at baseline. We have treated 10 adult patients (between 18 and 33 years old) in the dose escalation phase of our Phase 1/2 clinical trial. These 10 patients were dosed in three cohorts with escalating doses of  $1E^{11}$  vg/mL (cohort one),  $3E^{11}$  vg/mL (cohort two) and  $1E^{12}$  vg/mL (cohort three) of AAV-CNGB3.

In each of the 10 adult patients treated and one pediatric patient treated, the macula, including the fovea, was covered by the subretinal injection. Subretinal injections have been administered by two different surgeons at the Moorfields Eye Hospital in London.

In adult *CNGB3* patients, treatment of the central retina with our AAV-CNGB3 product candidate via subretinal injection has been generally well tolerated. Following the review of the safety data for each cohort treated in this study, the independent monitoring committee, or IDMC, recommended escalation to the higher dose in the next cohort. Data from the first adult treatment cohort along with our preclinical data of AAV-CNGB3 was used to support our PRIME designation that was awarded by the EMA in February 2018.

As of May 4, 2018, all three patients in cohort one and the first patient in cohort two have completed the first six months of follow up after treatment and have moved into the long term follow up protocol. In this timeframe we have not yet observed changes in visual function assessment in these adult patients. However, we have observed signs of improvement in measurements of photoaversion in two of the four patients in the treated eye compared to baseline. This preliminary observation has been observed at both the three and six month assessments following treatment in both patients. This is preliminary data and measurements must be repeated at further time points and in additional patients to support any potential effect. In this clinical trial, photoaversion is assessed by measuring changes in the opening between the upper and lower eyelids, or the palpebral aperture, in response to exposure to light of 16.6 cd/cdm<sup>2</sup> in patients following treatment compared to pretreatment baseline. As discussed in *Investigative Ophthalmology & Visual Science* in 2017, this is a surrogate endpoint of photoaversion in ACHM patients.

We anticipate completing dosing in our *CNGB3* Phase 1/2 clinical trial, including the pediatric dosing, in the second half of 2018. We expect to release data from the adult dose escalation cohorts along with preliminary six month data from the pediatric patients in 2019.

With this data, we plan to meet with the regulatory agencies in 2019 to discuss the pivotal trial design and path to regulatory approval, with the aim of initiating a pivotal trial in *CNGB3* patients in 2019.

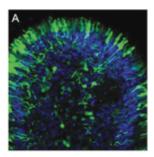
Our *CNGB*3 gene therapy product candidate, AAV-CNGB3, was granted orphan drug designation by the FDA and EMA, as well as rare pediatric disease designation by the FDA for the treatment of achromatopsia caused by mutations in the *CNGB*3 gene. We have also been granted PRIME designation by the EMA.

## ACHM Caused by Mutations in CNGA3

We are also developing AAV-CNGA3 to treat ACHM caused by mutations in the *CNGA3* gene. While the mechanism for treating *CNGA3* related ACHM is similar to that for *CNGB3*, we believe a larger amount of CNGA3 protein is required to restore cone function compared to CNGB3. We believe this may reflect the 1:3 ratio in which CNGB3:CNGA3 subunits associate to form the cone CNG channel. We have designed a synthetic promoter to drive high levels of CNGA3 expression specifically in cones. In preclinical studies, our novel cone specific promoter has been associated with strong gene expression in all human cone subtypes in human retinas grown *in vitro* using human pluripotent stem cells, or hPSC. AAV-CNGA3 utilizes this proprietary pan cone promoter to drive a codon optimized *CNGA3* gene sequence. We believe this novel promoter can drive sufficient expression of *CNGA3* in cones to restore light sensitivity to these cones in CNGA3 deficient patients. We use the AAV8 capsid to transfect cone photoreceptors in the back of the eye and we target the cones concentrated in the central region of the retina via a subretinal injection that covers the macula.

A key aspect of developing an effective treatment for ACHM caused by *CNGA3* mutations is a promoter that drives robust gene expression in all of the three different cone subtypes, S/blue, L/red and M/green. In particular, it is important to evaluate the activity of the promoter in human photoreceptors, which can be achieved prior to treating patients using human stem cell derived retinas. Our relationship with UCL provides access to what we believe is one of the few centers in the world that can generate human "mini retinas," or HMRs, which are human retinas grown *in vitro* from hPSCs. These HMRs develop from stem cells over several months to form primary photoreceptors arrayed in a spherical structure that resembles many aspects of the human retina and includes all the rod and cone subtypes, allowing us to assess and predict the utility of many aspects of gene therapy vectors for human clinical application.

In vitro studies to measure the gene expression driven by our cone specific promoter in human cones using HMRs were conducted at UCL IO during 2017. Figure 4A shows a fully formed HMR that has been transfected with a construct in which our cone specific promoter was associated with the expression of green fluorescent protein, or GFP, a green marker gene. The expression of GFP is seen specifically in cone photoreceptors throughout this HMR, indicating that our promoter is driving robust gene expression in human cones. To support that this promoter drives gene expression in all cone subtypes, GFP expression driven by our promoter was overlaid with markers specific to each of the cone types. Figure 4B is an image of an S/blue cone and Figure 4C is an image of an L/red cone and an M/green cone, with the cone-specific marker labeled in red in each case. The multiple colors in Figures 4B' and 4C' show the overlay of these cone-specific markers with cone specific GFP expression, indicating that our promoter drives gene expression in all cone subtypes in this HMR. The data from these studies have not been published.



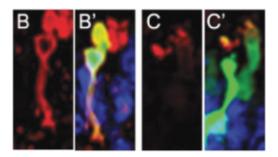


Figure 4A. An hPSC derived HMR showing GFP expression (green) driven by our promoter in human cones throughout the HMR.

**Figure 4B.** The red marker identifies this cone as an S/blue cone.

**Figure 4B'.** An overlay of GFP expression from our promotor on top of the S/blue cone specific marker. The overlap between the cone marker and GFP expression indicates that our promoter drives gene expression in S/blue cones.

**Figure 4C.** The red marker identifies M/red and L/green cones.

**Figure 4C'.** An overlay of GFP expression from our promotor on top of the M/Red and L/green cone specific marker. The overlap between the cone marker and GFP expression indicates that our promoter drives gene expression in M/red and L/green cones.

In preclinical studies of mutant mice lacking the *Cnga3* gene conducted at UCL IO during 2017 and 2018, treatment of retinas of *Cnga3* mutant mice with AAV-CNGA3 was associated with restoration of the cone electrical response following subretinal delivery. Figure 5 and Figure 6 show the rescue of cone function that was observed in two of these studies with doses spanning those proposed in the clinical trial and in a dose dependent manner. We believe this supports the evaluation of AAV-CNGA3 to treat patients with ACHM caused by mutations in *CNGA3* in a Phase 1/2 clinical trial. The data from these studies have not been published.

light.

Figure 5 shows the electrical response of retinas to a single flash of bright light. A retina from three different mice were tested: a normal mouse (Figure 5A), a mutant mouse lacking the *Cnga3* gene (Figure 5B) and a mutant mouse lacking the *Cnga3* gene, but treated with 3uL of 1E<sup>12</sup> vg/mL AAV-CNGA3 (Figure 5C). A high degree of restoration of function of mutant cones was observed in the retina from the *Cnga3* mutant mouse treated with AAV-CNGA3, with approximately 60% of the electrical response to a bright flash of light of the normal retina observed in the retina from the *Cnga3* mutant mouse that were treated with AAV-CNGA3. The mice were injected with AAV-CNGA3 at four weeks of age and assessed using ERG four weeks post injection.

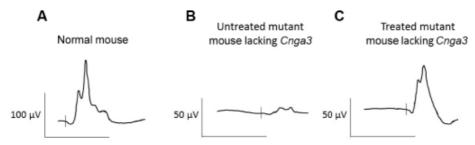


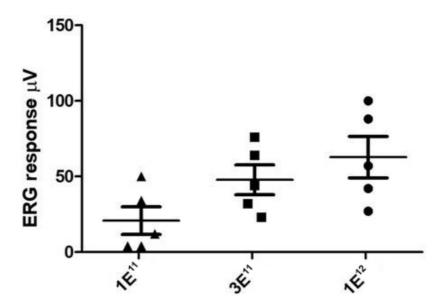
Figure 5. Cone electrical response in mice retinas reacting to a single flash of bright light, measured by ERG.

**Figure 5A**. The electrical response of the retina from a normal mouse reacting to a flash of bright light.

**Figure 5B**. The electrical response of the retina from a mutant mouse lacking *Cnga3* reacting to a flash of bright light.

**Figure 5C**. The electrical response of the retina from a mutant mouse lacking *Cnga3* treated with AAV-CNGA3 reacting to a flash of bright

Figure 6 shows the cone-mediated ERG responses measured in *Cnga3* mutant mice treated with three different doses of AAV-CNGA3. 3uL of AAV-CNGA3 was administered via subretinal injection in each eye at 1E<sup>11</sup> vg/mL (n=5), 3E<sup>11</sup> vg/mL (n=5) and 1E<sup>12</sup> vg/mL (n=5). The mice were treated at 15 days old and the ERG was measured four weeks after treatment. The reviewer analyzing the ERG responses was masked to which eye received treatment. Doses tested in this study span the doses of AAV-CNGA3 proposed for our Phase 1/2 clinical trial. Figure 6 shows the ERG responses that were observed at each of the three doses.



**Figure 6**. The photopic ERG amplitudes measured to assess cone photoreceptor function in Cnga3 mutant mice treated with AAV-CNGA3 at doses of  $1E^{11}$  vg/mL (n=5),  $3E^{11}$  vg/mL (n=5) and  $1E^{12}$  vg/mL (n=5). Mice were treated at 15 days post-natal and ERGs were assessed four weeks following treatment. The retinal ERGs are the electrical recordings corresponding to cone activity following a single pulse of bright light. A dose response was observed in retinal sensitivity obtained using the three tested doses and a treatment effect was also observed in the lowest dose tested.

In 2018, we anticipate completing a toxicology package similar to that used with the AAV-RPGR program using cGMP AAV-CNGA3 material manufactured at our cGMP facility. We anticipate conducting an approximately six month toxicology study in mice and two, eight week acute toxicology and biodistribution studies in mice and rabbits. The long-term toxicology study initiated in the first quarter of 2018.

## Clinical development of AAV-CNGA3

We have an ongoing natural history study in ACHM including over 90 patients that allows us to collect structural and functional data for up to five years on prospectively defined endpoints, including functional tests (visual acuity, contrast sensitivity, mobility maze and photoaversion assessments), retinal imaging (color fundus photography, fundus autofluoresence imaging, spectral domain optical coherence tomography and visual field testing) and electrophysiological assessments. The study center is the Moorfields Eye Hospital in London. We believe access to these ACHM patients will enable us to efficiently enroll appropriate patients into our *CNGA3* Phase 1/2 clinical trial. In addition to giving us access to patients and potentially accelerated enrollment in our treatment study, we believe the prospective natural history data on each treated patient will allow us to gather robust data from our Phase 1/2 clinical trial in a condensed timeframe.

We aim to initiate a Phase 1/2 dose escalating trial of AAV-CNGA3 in ACHM patients with mutations in *CNGA3*. We expect this clinical trial will have the same design as our ongoing AAV-CNGB3 Phase 1/2 clinical trial and will initially be conducted in both adult and pediatric patients at two sites in the United States and Europe. AAV-CNGA3 clinical material is currently being manufactured at our cGMP facility. We expect to release material for this trial in early 2019 and open a Phase 1/2 dose escalation trial in *CNGA3* patients shortly thereafter.

## X-Linked Retinitis Pigmentosa

Disease Background and Market Opportunity

Retinitis pigmentosa, or RP, is a group of IRDs which represent the most common genetic cause of blindness. The condition is characterized by progressive retinal degeneration and vision loss that ends in complete blindness. There are currently no approved treatments for RP. We believe gene therapy is a promising therapeutic approach. RP initially presents as nighttime blindness during childhood or early adulthood, progressing to peripheral visual field loss and "tunnel vision," central visual impairment, reduced visual acuity and, ultimately, complete blindness.

RP may be caused by mutations in any of over 100 different genes. The most severe forms of RP are X-linked, or XLRP, with onset in early childhood and rapid progression to blindness generally by the time patients reach 30 to 40 years old. RP has an estimated prevalence of one in 3,500 in the United States, and between 10% and 15% of RP patients are estimated to suffer from XLRP. The most frequent mutation causing XLRP is in the retinitis pigmentosa GTPase regulator gene, or *RPGR*. XLRP associated with a mutation in RPGR, or XLRP-RPGR, accounts for more than 70% of cases of XLRP. There are estimated to be approximately 20,000 XLRP-RPGR patients in the United States, Japan and EU5, with a little less than 50% those patients being under the age of 40 and approximately 200 new cases being diagnosed annually. We believe the availability of a therapeutic option may increase patient identification and the estimated prevalence of XLRP-RPGR.

The RPGR protein has an essential role in the maintenance of the structure and function of both rod and cone photoreceptors. The RPGR protein is tightly localized in the photoreceptors at the junction of the inner and outer segments, or cilium, of the photoreceptors. Correct localization of the RPGR protein to this site is important for the transport of light sensing proteins to the outer part of the photoreceptors, where these proteins convert light signals into electrical signals. In the absence of the RPGR protein the movement of light sensing protein within both rods and cones is impaired, leading to dysfunction and death of photoreceptors, resulting in retinal degeneration and ultimately complete blindness.

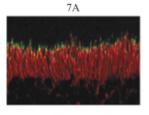
Our Gene Therapy Program

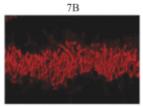
Our product candidate for the treatment of XLRP, AAV-RPGR, is designed to treat XLRP caused by mutations in *RPGR*, the most common form of XLRP. The eye specific form of RPGR is encoded by a nucleotide sequence called RPGR open reading frame 15, or *RPGR-ORF 15*. Both rods and cones photoreceptors require *RPGR-ORF 15* to function. The protein coding message *RPGR-ORF 15* contains a region of repeated sequences that make the *RPGR-ORF 15* nucleotide sequence unstable in the cell. We have engineered a small deletion in *RPGR-ORF 15* that we observed was associated with a stable sequence that rescued RPGR protein levels, localization and function in mouse and human photoreceptors in preclinical studies. Our novel AAV-RPGR viral vector utilizes the human rhodopsin kinase, or RK, promoter to specifically drive the expression of our stabilized *RPGR-ORF 15* in both rods and cones. We selected the AAV5 capsid because of its efficient transfection into both of these types of photoreceptors.

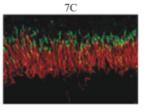
In preclinical studies, performed at UCL IO between 2009 and 2015 and discussed in *Gene Therapy* in 2016, it was observed that treatment with AAV-RPGR containing our stabilized *RPGR-ORF15* was associated with rescue of the *Rpgr* mutant phenotype in mice that completely lacked the RPGR protein as measured by ERG responses of retinas from *Rpgr* mutant mice and assessments of RPGR protein. Restored levels, localization and function of RPGR protein in mutant mice lacking the *Rpgr* gene were observed, along with the restoration and localization of photosensitive proteins in both rod and cone photoreceptors, and reduction of long-term retinal degeneration. In addition to these experiments in *Rpgr* mutant mice, we have observed that our *RPGR-ORF 15* construct also rescued levels, localization and function of RPGR protein in human photoreceptors, in HMRs derived from patients with *RPGR* mutations. We believe that AAV-RPGR may have the potential to positively impact human photoreceptor function and survival in XLRP-RPGR patients, slowing or halting the degeneration that leads to blindness in these patients.

Figure 7 and Figure 8 show data from these preclinical studies regarding the effect of subretinal delivery of AAV-RPGR containing our stabilized *RPGR-ORF 15* in mice lacking the *Rpgr* gene. In these studies, different color stains were used to investigate the restoration of (i) RPGR protein expression, (ii) correct localization of RPGR protein and (iii) RPGR function. Figure 7 and Figure 8 show a retina from a normal mouse (7A and 8A), a retina from a mutant mouse strain lacking the gene for *Rpgr* (7B and 8B) and a retina from the same mutant mouse strain that lacks the gene for *Rpgr*, but treated with AAV-RPGR containing our stabilized *RPGR-ORF 15* (7C and 8C).

The red stain in Figure 7 marks a photoreceptor protein, rootletin, within the cilium, or middle section, of every photoreceptor, while the green stain reveals the localization of RPGR protein. The green stain in Figure 7A shows the localization of RPGR protein within the photoreceptor at the end of the cilium in a normal mouse retina. Figure 7B shows a retina from a mouse lacking the *Rpgr* gene without any green staining, indicating the absence of the RPGR protein. Figure 7C shows a retina from a mouse lacking the *Rpgr* gene that was treated with AAV-RPGR containing our stabilized *RPGR-ORF 15*. The green staining at the end of the photoreceptor cilium is similar to the normal mouse retina. Treatment with AAV-RPGR containing our stabilized *RPGR-ORF 15* was associated with the restoration of RPGR protein expression and localization within the individual photoreceptor cells consistent with normal RPGR expression.







Normal RPGR expression

Untreated mutant lacking RPGR

Treated mutant lacking RPGR

**Figure 7.** In these preclinical mouse models, the red staining marks a normal protein in the photoreceptor cilia, rootletin, while the green stain reveals localization of RPGR protein within the photoreceptor.

Figure 7A. The retina from a normal mouse.

**Figure 7B.** The retina from a mouse completely lacking the *Rpgr* gene.

**Figure 7C.** The retina from a mouse completely lacking the *Rpgr* gene and treated with AAV-RPGR containing our stabilized *RPGR-ORF 15*. The green stain indicates that RPGR protein expression was restored and was similarly localized within the individual photoreceptor consistent with normal RPGR expression.

Figure 8 shows a different analysis of retinas from the same mutant mouse strain that completely lacks the gene for *RPGR* expression. This analysis uses a yellow tag to reveal the location of photoreceptor light pigment, or opsins. The top row shows the rod opsin (8A; 8B; 8C), rhodopsin, and the bottom row shows cone opsin (8A'; 8B'; 8C'). Fully functional RPGR is critical for the correct localization of opsins and Figures 8B and 8B' show that in a *Rpgr* mutant mouse retina the opsins are incorrectly localized. Figures 8C and 8C' show that treatment of these mutant animals with subretinal injection of AAV-RPGR containing our stabilized *RPGR-ORF 15* enabled the correct location of the opsins within the photoreceptor as seen in the similarity to the normal mouse, indicating that RPGR is functionally active in supporting correct localization of key photoreceptor proteins.

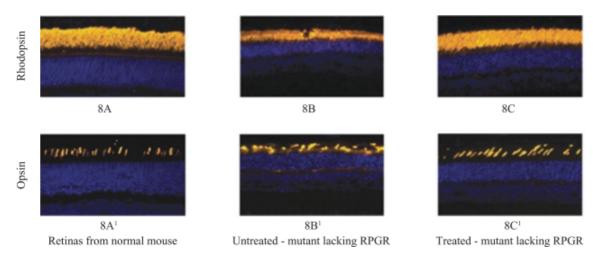


Figure 8. In these preclinical mouse experiments, a yellow tag reveals the location of the opsins.

Figures 8A and 8A'. Normal mouse retina showing the localization of rhodopsin and opsin.

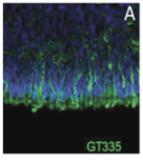
Figures 8B and 8B'. Rpgr mutant mouse retina showing the localization of rhodopsin and opsin.

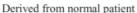
**Figures 8C and 8C'.** *Rpgr* mutant mouse retina that was treated with AAV-RPGR containing our stabilized *RPGR-ORF 15* shows the localization of rhodopsin and opsin. The similar localization between the normal mouse retina and the *Rpgr* mutant mouse retina that was treated with AAV-RPGR containing our stabilized *RPGR-ORF 15* indicates that the rhodopsin and opsin are correctly localized and can perform their key function in the visual cycle.

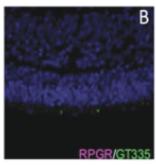
We are further advancing the HMR system to evaluate the potential for our product candidates to functionally restore mutant photoreceptor cells in a human retina.

One of the many tasks that *RPGR* performs in the photoreceptor is to enable a process called glutamylation of a key cilia protein called tubulin, which is required for photoreceptor function. We conducted an *in vitro* study at UCL IO in 2016 using HMRs derived from stem cells from XLRP-RPGR patients to determine the effect of AAV-RPGR containing our stabilized *RPGR-ORF 15* on human photoreceptors. The data from this study has not been published. An HMR grown from hPSC from a normal individual is shown in Figure 9A, in which glutamylation of tubulin in normal human photoreceptors is stained in green. Figure 9B shows a HMR derived from a XLRP-RPGR patient and cultured over several months to form many of the anatomic layers of the retina and consisting of all photoreceptor types, while Figure 9C shows the impact of AAV-RPGR containing our stabilized *RPGR-ORF 15* treatment on a similarly cultured HMR derived from a XLRP-RPGR patient.

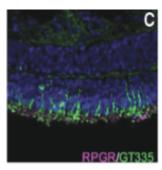
The HMR derived from a XLRP-RPGR patient lacks RPGR protein, making the photoreceptors dysfunctional with no glutamylation of tubulin present (Figure 9B). When HMRs from a XLRP-RPGR patient were treated with AAV-RPGR containing our stabilized *RPGR-ORF 15* we observed that glutamylation of tubulin returned (Figure 9C). We also stained HMRs derived from an XLRP-RPGR patient with a pink marker of RPGR protein. In Figure 9B no pink staining was observed, confirming the lack of RPGR protein. In Figure 9C, when the HMR from a XLRP-RPGR patient was treated with AAV-RPGR containing our stabilized *RPGR-ORF 15*, pink staining can be seen at the correct localization in the base of the cilium of the photoreceptors that are now stained with green glutamylation of tubulin marker. This restoration of RPGR protein expression and localization, and restoration of markers of photoreceptor function in human photoreceptors in HMRs derived from XLRP-RPGR patients, indicates potential clinical utility of AAV-RPGR containing our stabilized *RPGR-ORF 15*.







Untreated - Derived from XLRP-RPGR patient



Treated - Derived from XLRP-RPGR patient

**Figure 9.** A HMR derived from hPSCs from a normal individual (9A) or a XLRP-RPGR patient (9B and 9C) cultured over several months to form many of the anatomic layers of the retina and consisting of all photoreceptor types with the glutamylation of tubulin having a green fluorescent stain.

Figure 9A. A HMR derived from normal hPSCs.

**Figure 9B.** A HMR derived from a XLRP-RPGR patient.

**Figure 9C.** A HMR derived from a XLRP-RPGR patient that was treated with AAV-RPGR containing our stabilized *RPGR-ORF 15*. The appearance of pink RPGR protein at the base of the photoreceptor cilium and glutamylation of tubulin returns, demonstrating the restoration of RPGR protein expression, localization and function.

To support the advancement of AAV-RPGR into clinical development, we conducted three single-dose toxicology studies from January 2016 to August 2017 at UCL IO. We performed a six month toxicology study in normal mice delivering doses of saline in both eyes for the control (n=5), and doses of AAV-RPGR in both eyes of 2E9 vg/eye (n=5) and 4E9 vg/eye (n=5), with a toxicology assessment at one, three and six months post-administration. Two further toxicology studies were performed. An eight week mouse study in which groups of mice were dosed with saline in both eyes as a control (n=15), AAV-RPGR in both eyes at 1E9 vg/eye (n=15) or AAV-RPGR in both eyes at 4E9 vg/eye (n=15), providing five mice from each group for studying local and systemic effects at each time-point of one, four and eight weeks after treatment. An eight week rabbit study was also conducted, in which nine right eyes were dosed per group, with doses of saline as a control, and AAV-RPGR doses of 0.8E11 vg/eye and 2.4E11 vg/eye, providing three rabbits for studying local and systemic effects at each time-point of one, four and eight weeks after treatment. Biodistribution was examined in the eight week mouse and rabbit studies. No harmful effects on the retina or systemically were observed. We used these data to support our CTA and IND for treatment of XLRP-RPGR patients with AAV-RPGR.

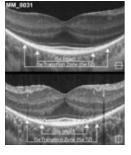
## Clinical Development of AAV-RPGR

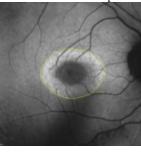
We have an ongoing natural history study in XLRP-RPGR including approximately 100 patients, which allows us to collect structural and functional data for up to five years on prospectively defined endpoints,

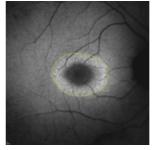
including functional tests (visual acuity and contrast sensitivity), retinal imaging (color fundus photography, fundus autofluoresence imaging, spectral domain optical coherence tomography, adaptive optics and visual field testing) and electrophysiological assessments. The study centers are the Moorfields Eye Hospital in London, the Kellogg Eye Center at the University of Michigan, the Medical College of Wisconsin & Froedtert Hospital and Massachusetts Eye and Ear. We believe access to this large population of XLRP-RPGR patients has enabled us to efficiently enroll appropriate patients into our XLRP-RPGR Phase 1/2 clinical trial. In addition to giving us access to patients and potentially accelerated enrollment in our treatment studies, we believe the prospective natural history data on each treated patient will allow us to gather robust data from our Phase 1/2 clinical trial in a condensed timeframe. Of particular interest is the area and width of the ellipsoid zone, which is a validated surrogate marker of retinal degeneration in RP and other IRDs.

The ellipsoid zone is a marker of retinal structure observed by optical coherence tomography, or OCT, and has been demonstrated to contract as the retina degenerates in a number of different IRDs. The ellipsoid zone has been shown to progressively decrease over time in step with the degeneration of the retina that occurs in XLRP-RPGR patients. Our natural history study provides data on ellipsoid zone width and area for up to five years prior to treatment with AAV-RPGR for each patient that then enrolls in our gene therapy treatment trial.

Figure 10 shows two sets of images taken 24 months apart using OCT and fundus autofluorescent imaging, two imaging techniques used to capture micrometer-resolution images of the eye, of the ellipsoid zone of one XLRP-RPGR patient in the natural history study. This patient was 20 years old upon entering the study when the first assessment was taken. Measurements associated with these images show that the ellipsoid zone area decreased from 10.98 mm² to 7.94mm² and the width of the ellipsoid zone decreased from 2830 microns to 2204 microns over 24 months.







10A 10B

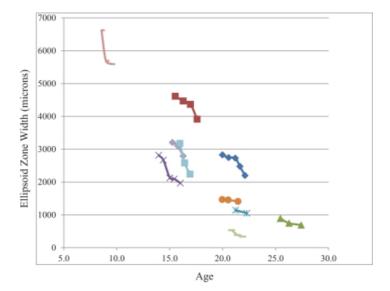
**Figure 10.** OCT and fundus autofluorescence images of the ellipsoid zone of one RPGR-XLRP patient in the natural history study taken 24 months apart. During the 24 month time frame the width and area of the ellipsoid zone have diminished.

Figure 10A. These two OCT images, taken 24 months apart at the same position in the retina, illustrates the width of the ellipsoid zone.

**Figure 10B.** These two images show the fundus autofluorescence imaging of the same retina taken 24 months apart. The fovea is located approximately in the center of the ring and can be seen as a slightly darker dot. The outlined "autofluorescent" area was reduced over the 24 months between the capture of the two images.

A further benefit of the XLRP-RPGR natural history study is access to longitudinal data from the population of XLRP-RPGR patients over time. Figure 11 is a graph of data collected in our XLRP-RPGR natural history study of individual patients, which evidence a relationship between a patient's ellipsoid zone width and age. These data show a reduction in ellipsoid zone width over time in each patient, as well as the increased rate of

decline in younger individuals. We believe these data will support both our Phase 1/2 clinical trial and any future pivotal trial by enabling us to select patients with similar characteristics and rate of disease progression for treatment with AAV-RPGR, as well as providing longitudinal and individual patient data on the rate of ellipsoid zone shrinkage to more readily assess the impact of therapeutic intervention.



**Figure 11.** Graph of data gathered in our XLRP-RPGR natural history study showing the correlation between ellipsoid zone width (Y-axis) and age (X-axis) in individual patients.

We are conducting a Phase 1/2 clinical trial of AAV-RPGR in both adult and pediatric XLRP-RPGR patients. This trial is open in the United Kingdom under our CTA and United States under our IND. In the dose escalation phase of the trial, up to 18 adult patients may be administered one of three different doses of vector in dose escalating cohorts of three to six patients at a time. Once an acceptable safety profile has been established in adults, up to 18 adults or children may then be treated at an acceptable dose. We expect to begin enrolling patients in this expansion cohort in the second half of 2018. The primary endpoint of this open-label, dose-escalation clinical trial is the safety of delivering AAV-RPGR through subretinal injection. Secondary endpoints include the outcomes of a range of functional tests, quality of life measures and detailed analysis of the retina, including structural analysis of individual photoreceptors and measurements of ellipsoid zone via optical coherence tomography and fundus autofluorescence ring size. Following discussions with the FDA, we will be splitting the extension cohort into two groups to be treated with two different doses of AAV-RPGR. We will look at a range of functional and structural assessments including the ellipsoid zone progression as an acceptable surrogate marker of retinal degeneration with the aim of gaining early data on the activity of our potential gene therapy product in this patient population. Retinal images of treated and untreated fellow eyes at different time-points will be read at an independent reading center and evaluators will be blinded to treatment.

RP initially presents as nighttime blindness during childhood or early adulthood, progressing to peripheral visual field loss and "tunnel vision," central visual impairment, reduced visual acuity and, ultimately, complete blindness. XLRP-RPGR is a progressive disease in which the retina gradually degenerates starting in the outer, or peripheral, regions of the retina and initially causing "tunnel vision" with final degeneration of the central retina resulting in the complete loss of visual acuity and blindness that generally occurs by the time patients are 30 to 40 years old. We believe that to prevent this ultimate degeneration to blindness and to retain visual acuity, the central region of the retina, including the macula and fovea, must be preserved. To this end, we aim to deliver AAV-RPGR to this central region of the retina. In our Phase 1/2 clinical trial, AAV-RPGR viral vector is delivered via subretinal injection of up to 1mL with the potential for the surgeon to use multiple

retinotomies targeting the region of the central retina, including the macula and fovea. One eye is treated in each patient, which is the eye assessed to be the worst eye at baseline.

We have treated seven adult (aged 19 to 30 years old) patients in the Phase 1/2 XLRP-RPGR clinical trial, three patients in cohort one at a dose of  $1E^{11}$  vg/ml and four patients in cohort two at a dose of  $2E^{11}$ vg/ml. In all patients, subretinal injection covered the central part of the retina, including the macula and fovea. Following review of the safety data from cohort one of this trial, the IDMC recommended escalation of dose in the second cohort.

As of May 4, 2018, we have three month data on the three patients in cohort one, with one patient reaching six months post treatment. While preliminary, we observed indications of improved retinal sensitivity in the first two patients in cohort one as assessed by two different measures of retinal sensitivity, navigation of the mobility maze in dim lighting conditions and perimetry using the Octopus 900 perimeter to assess the sensitivity of the central retinal field. The Octopus 900 perimeter assesses light sensitivity across the retinal field by measuring patients response to small spots of light in a grid. In both of these patients, data from Octopus 900 perimetry assessments compared to baseline measurements showed signs of improvement in retinal sensitivity at three months following treatment, with continued signs of improvement in the first patient to reach the six month post-treatment assessment. In both patients we also observed improvement in the speed and error rate of navigating the mobility maze at low light levels (one lux) at the three month assessment following treatment compared to pretreatment baseline in the treated eye and not in the untreated eye. This early signal of improvement in two assessments of photoreceptor function in XLRP-RPGR patients following treatment with AAV-RPGR is encouraging. However, this is preliminary data and needs to be supported by data collected at later time-points and in larger numbers of patients in future cohorts.

We anticipate completing adult dosing in this Phase 1/2 clinical trial during the third quarter of 2018, and completing the dosing of the two pediatric cohorts in 2019. We expect preliminary data from the dose escalation phase to be available during the first half of 2019.

We will close out this trial 18 months after the last pediatric patient has been treated. Patients will then move into a long-term follow up study for safety and indication of benefit for an additional three and a half years.

The FDA and EMA have granted orphan status to AAV-RPGR for the treatment of retinitis pigmentosa. The FDA has also granted fast track designation to AAV-RPGR for the treatment of XLRP caused by defects in *RPGR*.

#### RPE65-Deficiency

Disease Background and Market Opportunity

*RPE65*-deficiency causes rod photoreceptor dysfunction and impaired vision from birth. The *RPE65* gene encodes a protein that is produced in the retinal pigment epithelium, or RPE, a thin layer of cells at the back of the eye that support photoreceptors and nourish the retina. The RPE65 protein is essential for rod function because it recycles the light sensing machinery in rod photoreceptors. Absence of RPE65 results in severe dysfunction of rods and causes impaired vision in dim lighting conditions. Although cone photoreceptors are generally preserved during childhood in *RPE65*-deficient patients, the lack of function and degeneration of the rods eventually results in the loss of cones and degeneration of the whole retina over time. Consequently, most *RPE65*-deficient patients experience central vision loss progressing to complete blindness by early adulthood.

*RPE65*-deficiency is often characterized as a specific subtype of Leber congenital amaurosis or RP that is caused by mutations in the *RPE65* gene, called Leber congenital amaurosis 2 and RP20, respectively. However, we believe a more precise approach to genetic diseases is to focus on the underlying genetic defect, rather than the phenotype, and have therefore identified *RPE65*-deficiency as the target of our product candidate AAV-RPE65.

Based on an estimated prevalence of approximately one in 500,000 people in the United States suffering from Leber congenital amaurosis, or LCA, related to mutations in the *RPE65* gene, and approximately one in 70,000 people in the United States having RP due to mutations in the *RPE65* gene, *RPE65*-deficiency occurs in approximately one in 125,000 people in the United States. There are estimated to be approximately 6,000 *RPE65*-deficiency patients in the United States, Japan and EU5, with almost 30% of those patients being under the age of 30 and approximately 50 new cases being diagnosed annually. We believe the availability of a therapeutic option may increase patient identification and estimated prevalence of *RPE65*-deficiency.

Our Gene Therapy Program

Our gene therapy candidate for the treatment of *RPE65*-deficiency, AAV-RPE65, is an AAV2/5 viral vector, in which a codon optimized *RPE65* gene is driven by a novel synthetic RPE cell specific promoter.

*RPE65*-deficiency is a well validated condition for gene replacement therapy. In multiple clinical trials, including one conducted by our collaborators at UCL, replacing the mutant *RPE65* gene with a normal copy of the gene resulted in improved nighttime vision in affected children and young adults, suggesting the potential impact of gene therapy on rod function in this disease. The FDA recently approved the first gene treatment for *RPE65*-deficiency, Luxturna. While *RPE65*-deficiency primarily causes a loss of rod function initially leading to impaired vision in dim light, these patients ultimately experience complete blindness because of degeneration of the cone rich fovea. To prevent blindness, therefore, we believe it is critical to treat the central retina in order to maintain structural integrity in this region and save central vision. We aim to treat as extensive an area of the central retina as possible, including the cone rich fovea. Thus, in addition to improving rod function, we aim to provide sufficient RPE65 protein to the cells in the central retina to prevent the degeneration of both rods and cones in this region, and thereby prevent the progression to complete blindness.

We focus on detailed structural and functional data in our treatment studies with the aim of demonstrating an impact on the degeneration of the central retina.

Our novel AAV2/5 vector, AAV-RPE65, has been optimized for both transduction of RPE cells and RPE65 protein production and our surgical approach targets the central area of retina whose preservation is most critical for long term maintenance of visual function. Building on the work of Professor Ali and in collaboration with the team at UCL, we have developed AAV-RPE65. AAV-RPE65 is a second generation viral vector that has compared favorably to our first generation AAV2/2 vector in a number of ways, including being two to three logs, or 100 to 1,000 times, more potent on a particle for particle basis than our original AAV2/2 vector in a head to head *Rpe65* null animal model rescue experiment. On a logarithmic scale, each "log" represents a 10-fold change. We believe this increased potency will improve transgene expression and RPE65 protein production in the back of the eye. The table below summarizes elements of the optimization of AAV-RPE65 compared to our original AAV2/2 vector. Vector optimization studies were performed at UCL IO and were carried out from 2010 to 2015. The data summarized here was referred to in *Gene Therapy* in 2016. We used these data to support our IND and CTA for treatment of *RPE65*-deficient patients with AAV-RPE65.

Optimization of AAV2/5 compared to AAV2/2	
	Changing the capsid from AAV2/2 to AAV2/5 was associated with an improvement of the
Transfection Efficiency	transfection efficiency of RPE by four times.
Protein Expression (Promoter)	AAV2/5's optimized promoter was associated with a 20 times increase in protein expression.
	AAV2/5's optimized codon usage was associated with a seven times increase in protein expression
Protein Expression (Codon)	in human cells.
	Utilizing SV40 intron increases mRNA stability and was associated with a two and one half times
mRNA Stability	increase in protein production.
	The optimized construct was associated with a 300 to 1,000 times increase in efficacy in mouse
	functional rescue and is expected to be two to three logs more potent on a particle for particle basis
Overall Efficacy	in humans.

We conducted four single-dose toxicology and biodistribution studies of AAV-RPE65 from January 2015 to December 2016. We performed a long-term toxicology study in normal mice in which four eyes were

dosed with saline as a control and nine eyes were dosed with AAV-RPE65 at 4E<sup>9</sup> vg/eye, with a toxicology assessment at one, three, six and nine months post-administration. We also conducted an eight week mouse study, an eight week rabbit study and an eight week minipig study. In the mouse study, 15 mice were dosed in both eyes with saline as a control, 15 mice were dosed in both eyes with AAV-RPE65 at 1.2E<sup>9</sup> vg/eye and 15 mice were dosed in both eyes with AAV-RPE65 at 3.7E<sup>9</sup> vg/eye, providing five mice from each group for studying local and systemic effects at each time-point of one, four and eight weeks after treatment. In the rabbit study, nine rabbit's right eyes were dosed for each group with a saline control group, a 0.6E<sup>11</sup> vg/eye group and a 1.9E<sup>11</sup> vg/eye group, providing three animals from each group for studying local and systemic effects at each time-point of one, four and eight weeks after treatment. The minipig study was a two week single dose injection study in minipigs (n=2, each dosed in one eye) at a dose of 1.84E<sup>10</sup>11 vg/eye. The minipig study was performed by Charles River Laboratories, while the other three studies were performed at UCL IO. No harmful effects on the retina were observed during these studies. We used these data in support of our CTA and IND for treatment of *RPE65*-deficient patients with AAV-RPE65.

## Clinical development of AAV-RPE65

We have an ongoing natural history study in patients with *RPE65*-deficiency with approximately 30 patients enrolled that allows us to collect structural and functional data on prospectively defined endpoints, including functional tests (mobility maze, color vision, visual acuity and quality of life measures), retinal imaging (color fundus photography, fundus autofluoresence imaging, visual field testing, spectral domain optical coherence tomography and adaptive optics) and electrophysiological assessments. The study is global, with study centers including at the Moorfields Eye Hospital in London, University of Michigan Kellogg Eye Center and the Medical College of Wisconsin & Froedtert Hospital. We plan to present this natural history data to regulatory agencies in our meetings following completion of the Phase 1/2 clinical trial for discussion of our pivotal trial design and path to regulatory approval.

A Phase 1/2 clinical trial of AAV-RPE65 in both adult and pediatric patients is ongoing. The design of the trial is the same as our ACHM Phase 1/2 clinical trials. In the dose escalation phase of the trial, up to 18 adult participants may be administered one of three different doses of vector in dose escalating cohorts of three to six participants at a time. Once an acceptable safety profile has been established in adults, up to nine children may then be treated at an acceptable dose. The primary endpoint of this open-label, dose-escalation clinical trial is the safety of delivering AAV-RPE65 through subretinal injection in patients with *RPE65*-deficiency. Secondary endpoints include the outcomes of a range of functional tests, detailed structural analysis of the retina and quality of life measures.

This clinical trial is enrolling patients in the United Kingdom under our CTA, as well as the United States under our IND. We have treated 14 patients in this clinical trial and the first seven patients have consented to participate in the long-term follow up study. Children are currently being dosed in the United States and United Kingdom. Surgeries in this trial have been carried out in the United States at the University of Michigan Kellogg Eye Center and in the United Kingdom at the Moorfields Eye Hospital by three different surgeons. No differences in outcomes have been observed between the different surgeons.

In cohort one, three adults (aged 19, 20 and 20 years old) were administered up to 1 mL of  $1 \text{E}^{11}$  vg/mL of AAV-RPE65 vector. In each patient, the central region of the retina was targeted. No serious adverse events or dose limiting events have been reported in this cohort as of the 18 month time point following vector administration.

In each patient treated in cohort one, we observed improvement or stability in central visual function following treatment compared to baseline and compared to the untreated fellow eye. Retinal sensitivity was measured with threshold static perimetry using Octopus 900 perimetry and visual field modelling and analysis, or VFMA. Observations at 18 months following vector administration in the first cohort have demonstrated a

potential increase in retinal sensitivity by up to 40% from baseline. In contrast, we observed that the untreated eyes of patients in this cohort suffered a reduction in retinal sensitivity of up to 40%, which is in consistent with data from our parallel prospective natural history study of *RPE65*-deficient patients. In addition to the perimetry and VFMA data, improvements in time and error rate in mobility maze navigation have been observed in these patients at six and 12 months following treatment. However, this is preliminary data and needs to be supported by data collected at later time-points and in larger numbers of patients.

In addition to the functional data discussed above, we are collecting detailed structural data on all patients in our Phase 1/2 clinical trial. This includes data to visualize the mosaic of individual cones in the central part of the retina over time in each patient. We have sequential cone map data for more than 18 months following subretinal injections that covered the macula and fovea in the patients in cohort one, and as of May 4, 2018, we have not observed retinal thinning or loss of cones over time following treatment. We are continuing to monitor the detailed structure of both treated and untreated fellow eye in the five year follow on study to assess if AAV-RPE65 treatment has an impact on degeneration in the treated area of the eye compared to the untreated fellow eye.

In cohort two, three adults (aged 16, 20 and 22) were administered vector peripherally via subretinal injection into the outer region of the retina at a higher dose of up to 1 mL of  $3 \text{E}^{11}$  vg/mL. Following completion of the four week steroid taper, in two patients inflammatory responses were noted by the investigator as being probably related to vector administration. Both responded to a further course of steroids. Improvements in visual mobility in study eye over non-study eye were observed at 12 months at the four lux lighting level in this cohort. Similar increases in retinal sensitivity to cohort one have not been observed at this dose level. We believe data from cohort two is suggestive that peripheral administration of the vector into more degenerating areas of the retina may result in an increased chance of an immune response with a decreased potential benefit compared central administration of the vector. Following the review of the safety data for each adult cohort treated in this study, the IDMC recommended escalation to the higher dose in the next cohort.

Based on the safety and activity data from the patients treated at the  $1E^{11}$  vg/mL dose level (cohort one), the decision was made to treat pediatric patients at this dose prior to receiving the full safety data from adult cohort three, and to target the central part of the retina in all pediatric patients. Treatment of pediatric patients is currently ongoing in the United Kingdom and United States and five pediatric patients have been treated. We expect to treat one additional pediatric patient in this trial.

We carry out detailed assessments of retinal sensitivity across the entire retina, with the majority of tested retinal locations covering the central retina, at baseline and at prospectively defined time-points following treatment using the Octopus 900 perimeter. The Octopus 900 perimeter, unlike other standard clinical devices, enables full-field static perimetry using testing algorithms specifically designed for retinal conditions, affords the use of custom-developed testing grids, and allows the full dataset to be extracted and modelled for more accurate measurement of change over time.

Discreet small spots of light are shone onto multiple predetermined points (the test grid) covering the central retinal field and peripheral retina, with the patient responding each time they perceive a spot of light. Each point on the retina is tested multiple times with different intensities of light, thereby allowing the determination of both the reliability and reproducibility of the patients' response to each light level at each spot and an accurate measurement of the exact retinal sensitivity at topographically determined points. The data is read out as a 'heat map' of sensitivity across the retinal field. The reliability of the patient and the data produced is also calculated and provided by the machine. In addition to the heat map of retinal sensitivity and conventional mean sensitivity metric produced by Octopus 900 assessment, we also conduct advanced VFMA. This produces a volumetric measure of retinal sensitivity presented both numerically as well as in a topographical retinal sensitivity map, which better represents the entire dataset across the visual field. We compare the VFMA data from the retinal map at each timepoint following treatment to the baseline data to measure the extent and position of changes in retinal sensitivity over time in treated and untreated eyes.

As of May 4, 2018, we have received initial post-treatment Octopus 900 perimetry data in which we observed a strong response at the three month time-point in an 11 year old pediatric patient treated with AAV-RPE65 at a dose of  $1E^{11}$  vg/mL, one of the two pediatric patients we currently have follow up data from that time point on. However, this is preliminary data and needs to be supported by data collected at later time-points and in larger numbers of patients. Figure 12 shows the 'heat maps' produced by Octopus 900 assessment showing the light sensitivity across the retinal fields of the left (Figure 12A) and right (Figure 12B) eyes of this 11 year old *RPE65* patient at baseline prior to treatment with AAV-RPE65. Figure 13 shows the 'heat maps' produced by Octopus 900 assessment showing the light sensitivity across the retinal fields the untreated left eye (Figure 13A) and the treated right eye (Figure 13B) of this 11 year old *RPE65* patient at the first Octopus 900 assessment at three months following treatment with AAV-RE65 at a dose of  $1E^{11}$  vg/mL via subretinal injection covering the central retina including the macula and fovea.

The increased color observed in the patient's right eye in Figure 13 compared to the right eye in Figure 12, and especially the prominence of the green and yellow in the right eye, indicates a significant increase in light sensitivity in these areas of the retina. The reliability of this patient's data measured by the Octopus 900 perimeter scored the highest level achievable in the test. Reliability scores measured by Octopus 900 range from zero to 100, with 100 being totally unreliable and zero being the maximum reliability score. This patient achieved a reliability score of zero.

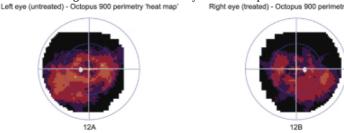
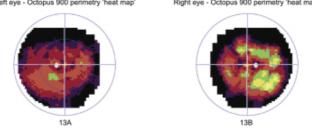


Figure 12. Image of the 'heat map' left and right eyes of an 11 year old patient produced prior to treatment with AAV-RPE65.



**Figure 13.** Image of the heat map left and right eyes of an 11 year old patient produced three months following treatment with AAV-RPE65 in the right eye, the left eye was untreated.

We anticipate completing dosing of the final pediatric patients in the second half of 2018. We will close out this trial six months after the last pediatric patient has been treated. Patients will then move into a long term follow up study in which patients will be followed for safety and an indication of benefit for an additional four and a half years.

Preliminary six month data from the full pediatric cohort will be available in the first half of 2019, along with top line data from the adults treated in the dose escalation phase of this study.

The FDA and EMA each granted orphan status to AAV-RPE65 for the treatment of LCA caused by mutations in *RPE65*. The FDA also granted AAV-RPE65 rare pediatric disease designation for the treatment of inherited retinal dystrophy due to biallelic *RPE65* mutations.

#### LCA4

#### Disease Background

LCA4 is an IRD that causes complete blindness before age five. AIPL1 is a central protein for the maintenance of photoreceptor structure and function. Deletion of the *AIPL1* gene causes the most severe form of early retinal dystrophy, LCA4, in which the retinal structure is destroyed with complete vision loss. LCA4 is rare, representing approximately 8% of all LCA cases.

There are currently no approved treatments for LCA4, and we believe an effective intervention will require introducing a normal functional copy of the *AIPL1* gene into rod and cone photoreceptors early in a patient's life while some retinal structure remains in order to activate function and survival of the photoreceptors that are still present. We believe gene therapy has the potential to be the only effective way to address the disease's root cause.

#### Our Gene Therapy Program

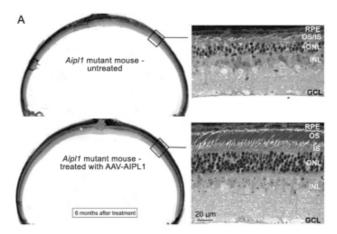
LCA4's extremely rapid progression, rarity and early age of onset make the standard process of seeking regulatory approval through clinical development challenging because adult safety trials would not yield meaningful data given the early onset of the disease. We believe we are well placed to initiate the first clinical intervention in this indication through our relationships with UCL and Moorfields Eye Hospital, whose expertise and large IRD patient population enables such an aggressive and uncommon IRD to be treated.

To address LCA4, we developed a viral vector to replace the *AIPL1* gene in all photoreceptors by using the *AIPL1* cDNA driven by the rhodopsin kinase promoter, which is active in both rods and cones.

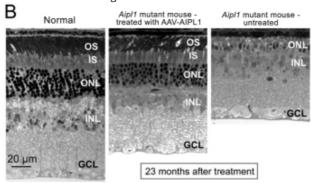
Much of the preclinical work to support the proof of concept for gene therapy in LCA4 was conducted by our collaborators at UCL IO, led by Professor Robin Ali, and was published in *Gene Therapy* in 2010.

Figure 14 and Figure 15 show histological sections revealing the structure of retinas from *Aipl1* mutant mice treated with AAV-AIPL1, compared to untreated retinas from *Aipl1* mutant mice, at six months and 23 months after treatment.

It was observed at both time-points that *Aipl1* mutant mice treated with AAV-AIPL1 suffered less photoreceptor loss than untreated *Aipl1* mutant mice, with the retinas of untreated mutant mice almost completely degenerated by 24 months of age. *Aipl1* mutant mice were treated with .5uL of AAV-AIPL1 at 1E<sup>12</sup> at four weeks post-natal and eyes were sectioned at six months and 23 months after treatment. These treated retinas were compared to retinas from untreated control *Aipl1* mice (n=17 eyes), and retinas from normal mice without the *Aipl1* mutantion sectioned at the same post-natal ages as the treated *Aipl* mutant mice. The data indicates that subretinal administration of AAV-AIPL1 is associated with the protection of the retina from degradation that occurs in *Aipl1* mutant mice, and this effect was durable out to two years, the oldest age studied in these mice.



**Figure 14.** Histological sections of retinas of *Aipl1* mutant mice treated with AAV-AIPL1 six months after treatment with AAV-AIPL1, compared to untreated retina. The top image is the retina of an untreated *Aipl1* mutant mouse at seven months post-natal. The lower image is the retina of a *Aipl1* mutant mouse at seven months post-natal, and six months following treatment with AAV-AIPL1.



**Figure 15.** Histological sections of retinas of *Aipl1* mutant mice treated with AAV-AIPL1 23 months after treatment with AAV-AIPL1, compared to untreated retina and retina from a normal mouse. The left image is the retina of an normal mouse at 24 months post-natal. The middle image is the retina of an *Aipl1* mutant mouse at 24 months post-natal, and 23 months following treatment with AAV-AIPL1. The right image is the retina of an untreated *Aipl1* mutant mouse at 24 months post-natal.

Clinical material was manufactured to cGMP standards under a specials license. Some of this clinical material was used in studies in 2017 at UCL to confirm potency in an AIPL1 deficient mouse and to perform toxicology testing in normal mice and rabbits. A potency study was conducted at a AAV-AIPL1 dose of 3E<sup>9</sup> vg/eye with a group size of three eyes. Assessments were performed at three weeks and supported the potency of the cGMP clinical material through analysis of the ERG response.

A toxicology study was performed with normal mice and rabbits. In the mouse portion, five animals per group were evaluated for local and systemic effects at four weeks. In the rabbit portion, three animals per group were evaluated for local and systemic effects at four and eight weeks. Safety evaluation included functional assessments using ERG, fundoscopy, and structural assessments.

Our product candidate, AAV-AIPL1, was manufactured and released for compassionate use under a specials license in the UK to treat LCA4 patients at the Moorfields Eye Hospital. This allows physicians at the

Moorfields Eye Hospital to prescribe a treatment of AAV-AIPL1 for LCA4 patients they deem appropriate. We play no role in the physician's treatment decision. We intend to use the data produced by the compassionate use treatment to inform any potential clinical development plan as well as any interactions with the regulatory agencies that would enable us to make this intervention more widely available to the LCA4 patient population. Although patients have been reviewed at the Moorfields Eye Hospital, so far none have been treated with AAV-AIPL1. As the manufacturer of AAV-AIPL1 under a specials license, we have a record retention requirement and a continuing obligation to inform the MHRA of any suspected adverse reaction to our medicinal product which is a serious adverse reaction.

The UK's Human Medicines Regulations 2012 allow for the manufacture and supply of medicinal products not authorized for marketing to patients with special needs at the request of the healthcare professional responsible for the patient's care (these products are referred to as "specials"). A special may only be supplied in: (i) response to an unsolicited order from a healthcare professional responsible for the care of the patient, (ii) if the product is manufactured and assembled in accordance with the specifications of that healthcare professional to fulfil the special needs of the individual patient that cannot be met by products already authorized for marketing and (iii) if the product is manufactured under a specials license granted by the UK's Medicines and Healthcare Products Regulatory Agency, or MHRA.

Manufacturing a special also imposes a five year record retention requirements subject to review by the MHRA, including details of any suspected adverse reaction to the product so sold or supplied of which the person is aware or subsequently becomes aware, as well as a continuing obligation to notify the MHRA of any suspected adverse reaction to the medicinal product which is a serious adverse reaction.

The FDA and EMA granted orphan designation to our product candidate, AAV-AIPL1, for treatment of inherited retina dystrophy due to defects in *AIPL1* gene.

## Age-Related Macular Degeneration (AMD)

Disease Background and Market Opportunity

AMD is a chronic eye condition that causes gradual decline of central vision. It is the leading cause of vision loss in individuals more than fifty years old in the United States and it affects 6.2 million people globally. Although AMD does not usually lead to complete blindness because peripheral vision is generally maintained, losing central vision has a critical impact on visual acuity, which is achieved by the closely packed cones of the central retina. As a result, loss of central retinal function has a significant impact on a person's independence and quality of life.

AMD is a complex disease attributed to several different causes. A number of genetic and environmental risk factors have been associated with the development of AMD. Two late forms of AMD have been characterized: geographic atrophy, or dry AMD, and neovascular AMD, or wet AMD. Dry AMD is characterized by the progressive, irreversible loss of many of the cell types in the retina, including the RPE, photoreceptors, and underlying capillaries of the macula, and causes a decline in central visual function. Wet AMD is defined by the growth and invasion of immature blood vessels from the underlying choroid into the retina. Leakage from these fragile blood vessels causes build-up of blood and fluid under the retina, leading to detachment of the RPE or retina and long term scarring.

Current therapeutic options for AMD are limited. There is no approved therapy that impacts the disease progression of dry AMD. The best available treatment for patients after they lose central vision and acuity is support and rehabilitation services to help them better utilize the remaining peripheral part of their retina.

Effective treatments for wet AMD are focused on blocking blood vessel growth, or angiogeneisis, that underlies the pathology of the disease. These wet AMD treatments specifically block the activity of vascular

endothelial growth factor, or VEGF, one of the key drivers of angiogenesis. There are two approved anti-VEGF treatments on the market, ranibizumab, or Lucentis, and aflibercept, or Eyelea. These may be effective in some wet AMD patients, but require challenging dosing regimens that typically include intra-ocular injections every one to three months.

#### **Our Gene Therapy Programs**

Wet AMD

We aim to use a gene-based strategy to deliver an anti-angiogenic molecule to the retina and create a "local factory" that will deliver a continual supply of antiangiogenic molecules to the key parts of the eye. This would require a one-time injection procedure to deliver the gene therapy to the affected eye. We focus our blockade on the receptor involved in driving aberrant blood vessel growth and leakage, VEGF Receptor 2, or VEGFR2. Rather than depleting the VEGF ligand from the system we aim to block the receptor for that ligand preventing VEGF binding to the receptor and thereby preventing downstream pathology of wet AMD that is normally triggered by VEGF binding to VEGFR2. We use an anti-VEGFR2 antibody. In some rodent models the inhibition of the VEGFR2 with this antibody appears to have reduced long term toxicity as compared to the depletion of the VEGF ligand. Initial studies have identified a lead candidate that we have now moved from the research stage to formal preclinical development. We are also working to integrate our gene regulation technology with our wet AMD program. Our ultimate aim is to activate the anti-VEGFR2 antibody gene that we have installed in the eye with a small molecule applied topically with an eye drop. This could potentially allow for intermittent dosing of the antibody using an eye drop rather than an injection.

Dry AMD - Rod to Cone Program

To treat dry AMD, and specifically to treat patients with geographic atrophy in which the central part of the retina is irreversibly damaged, we are advancing a novel strategy to alter the very character of rod photoreceptors.

In advanced forms of dry AMD, central visual function is lost after the fovea and the larger central retina area has degenerated, and any residual vision is generally via the outer retina's rods. A critical characteristic of cones that allows for response to high light levels is that they recover rapidly after they are stimulated by light. In contrast to cones, rods work in low light levels and require longer exposure to trigger an impulse and are then much slower to recover to a state when they can respond again. Therefore, seeing via rods is slow and imprecise, whereas cones mediate acute high resolution vision. By genetically engineering rods with molecules that will improve their speed of recovery and response to light, we aim to effectively transform a patch of rod photoreceptors to behave more like cones. This rod-to-cone transformation would potentially be achieved by using localized gene therapy vector placement in the rod-rich peripheral retina to create a small patch or "pseudo fovea," where cone like behavior of rods would enable the patient's brain to fixate on a functional part of the peripheral retina and recover a more cone like response to higher light levels.

The proof of concept has already been achieved in animal models, with first generation molecules designed to speed up the visual cycle recovery times in rods. We will continue to develop and optimize these molecules using our screening systems to allow selection for sensitivity to natural high light intensities and for the high refresh rate required.

#### Xerostomia

Disease Background and Market Opportunity—RIX

Radiation induced xerostomia, or RIX, is a severe and debilitating long-term side effect of radiation treatment for head and neck cancer. There is not currently any FDA approved treatment for RIX. Worldwide, there are approximately 500,000 new cases of head and neck cancer diagnosed each year, with approximately

50,000 cases in the United States alone, making it the fifth most common malignancy. Approximately 85% of patients who receive radiation treatment for head and neck cancer experience reduced saliva production during treatment, and approximately 40% of those patients who remain cancer free for two or more years after treatment continue to suffer from grade 2 or 3 RIX. There are approximately 170,000 such patients in the United States, with approximately 10,000 new cases each year. Severity of RIX is measured from grade 1 (mildest) to 4 (most severe). As these patients tend to be under the care of a physician and dentist and have access to some form of health insurance, we believe this is an accessible indication with much larger commercial potential than some genetic diseases that are currently targets of our gene therapy programs.

RIX is a frequent side effect of head and neck cancer treatment because the standard treatment of locally advanced head and neck cancer involves radiotherapy, which can cause irreversible damage to non-diseased tissues located near oral tumors, such as the salivary glands. The fluid secreting, or acinar cells, of the salivary glands are uniquely sensitive to radiation, are destroyed acutely on IR exposure and to a large extent do not regenerate, resulting in chronically reduced salivary output. Because saliva plays such a critical role in the physiology and protection of upper gastrointestinal, or GI, tract tissues, patients with chronic RIX suffer severe long term complications of head and neck irradiation that has a significant impact on the patient's daily living. Chronic RIX results in severe side effects, including difficulty swallowing, or dysphagia, oral discomfort, malnutrition, oral mucositis, changes in taste, increased oral infections and dental cavities.

Our Gene Therapy Program—RIX

Salivary glands are an attractive target organ for gene therapy treatments because they are self-contained, partially immune protected and easily accessible, allowing for non-invasive delivery of small vector doses.

We are developing AAV-AQP1 to treat RIX by increasing water conduction in the chronically damaged salivary glands by introducing a water conducting channel into the remaining epithelial cells of these damaged glands. Adequate water secretion by surviving epithelial cells has the potential to deliver the protective exocrine proteins produced by remaining gland cells into the mouth.

The key to our approach is that, unlike the water conducting acinar cells, the water impermeable duct cells of the glands appear to be resilient to IR exposure. As a consequence of this relative resilience to radiation treatment, salivary glands damaged by radiation treatment tend to contain mostly water impermeable ductal epithelial cells. To make these duct cells permeable to water, AAV-AQP1 introduces the gene for the human aquaporin water channel, or *hAQP1*. We have demonstrated that this has the potential to convey water permeability and causes ductal cells to generate an osmotic gradient, which causes them to secrete fluid into the lumen of the duct.

The proof of concept for this mechanism and its ability to increase the volume of saliva secreted by damaged salivary glands was observed in a Phase 1/2 clinical trial conducted by the U.S. National Institutes of Health, or NIH, in patients with chronic grade 2 or 3 RIX. The trial was designed as a short-term dose escalation trial of doses of AAV-AQP1 between 4.8E<sup>7</sup> and 5.8E<sup>9</sup> pu/gland using adenovirus as the vector to deliver the *hAQP1* to the remaining epithelial cells in the parotid gland of 11 patients suffering from chronic RIX. There were no reported severe adverse events among the patients treated, two out of three patients in each of the first three cohorts in this clinical trial were observed to have objective increases in saliva volume produced by the treated parotid gland, with increases in parotid flow ranging from 60% to 540%, and all but one of these patients showed a decrease in symptoms of dry mouth as measured by subjective visual analog scales, validated in other forms of xerostomia. The results of this study were published in *Proceedings of the National Academy of Sciences* in 2012.

We are currently conducting a Phase 1 dose escalation clinical trial in patients with grade 2 or 3 RIX who remain cancer free for at least five years after receiving radiation treatment. In this trial we are using AAV2 to deliver the *hAQP1* gene, as we believe AAV2 efficiently transfects the salivary gland cells and does not spread

beyond the target cells. Up to 18 adult patients may be administered doses of AAV-AQP1 between 3E<sup>9</sup> and 6E<sup>11</sup> viral particles per gland in dose escalation cohorts of three patients each. The aim of the trial is to determine the safety of inserting *hAQP1* locally into the salivary glands of RIX patients, as well as to measure changes in salivary flow resulting from the introduction of this channel. We have completed dosing in the first cohort and begun dosing in the second cohort, having treated five patients. This clinical trial is being conducted in conjunction with the National Institute of Dental and Craniofacial Research at the NIH Dental Clinic.

We expect to initiate an additional clinical trial at Memorial Sloan Kettering Cancer Center in the second half of 2018.

The FDA granted orphan drug designation for AAV-AQP1 to treat symptoms of grade 2 and grade 3 late xerostomia from parotid gland hypofunction caused by radiotherapy for cancer of the oral cavity.

Sjogren's Syndrome

The destruction of salivary tissue resulting in chronic xerostomia may also be caused by chronic autoimmune disease. Sjogren's syndrome is an autoimmune disease in which a patient's immune system may target the salivary glands. Chronic inflammation of the salivary glands results in long term damage and chronic xerostomia in many Sjogren's patients. Data from preclinical studies in animal models of Sjogren's syndrome and data from explants of minor salivary glands of Sjogren's patients suggest that Sjogren's syndrome may also be treatable with our AAV-AQP1 vector. Supported by data from our preclinical studies and our ongoing RIX clinical trials, we anticipate initiating a clinical trial of AAV-AQP1 for xerostomia caused by Sjogren's syndrome in 2019.

## **Neurodegenerative Diseases**

We also have research and preclinical programs targeting neurodegenerative diseases, with a research focus in ALS and Alzheimer's disease. In each of these diseases, we aim to target what we believe is a central factor in the underlying cell biology of the diseases, specifically RNA metabolism in ALS and endosomal trafficking dysfunction in Alzheimer's disease. Relying on our expertise in viral vector design, delivery, production and manufacturing, we are aiming to develop and optimize vectors to effectively treat both genetic and sporadic forms of these diseases.

#### ALS

Disease Background and Market Opportunity

ALS is a devastating, progressive, neurodegenerative disease leading to the loss of motor neurons, which are the neurons that control the ability to move, speak, swallow and ultimately to breathe. The gradual paralysis in ALS invariably leads to death. While 10% of ALS cases are caused by inherited genetic mutations, most ALS occurs sporadically, with no known genetic cause. Mutations in over 20 genes have been identified that cause the inherited ALS cases. Characterization of these disease-causing genes have implicated several cellular pathways in the disease, with a prominent role emerging for genes involved in the cellular control of RNA. Many new regulatory roles are being discovered for RNA, particularly in neurons.

One gene linked to ALS is the transactive response DNA-binding protein 43, or *TDP-43*. The TDP-43 protein is one of a number of proteins that binds to cellular RNA and regulates its function and stability. When *TDP-43* does not function normally, RNA regulation in the neurons loses its tight control and the motor neurons die. While mutations in *TDP-43* account for only about 0.5% of ALS cases, aggregates of TDP-43 protein are observed in motor neurons of more than 95% of all ALS patients, including both inherited and sporadic, and TDP-43 aggregation is a central feature of diseased motor neurons in ALS patients. *TDP-43*, therefore, may be a critical therapeutic target for the treatment of both sporadic and inherited forms of ALS. TDP-43 aggregates are also seen in approximately 50% of patients with frontotemporal dementia, or FTD, suggesting a potentially similar underlying mechanism of this neurodegenerative disease.

#### Our Gene Therapy Approach

Genetic approaches using yeast as the primary model system have been used to identify ways of protecting motor neurons from death in ALS. A genetic screen was conducted to look for activated genes that rescue the toxicity of TDP-43 aggregation. A group of fives genes that reduce TDP-43 toxicity, was identified including members of the nonsense mediated decay, or NMD, machinery, and two genes in particular: up frameshift protein 1, or *UPF1*, and up frameshift protein 2, or *UPF2*.

NMD is the quality control system regulating RNA processing and activity in all cells, and has additional and broader functions specifically in regulating RNA in neurons.

Over the past decade, increasing evidence suggests that motor neurons may be particularly vulnerable to defects in RNA regulation, which may be caused by a number of defects, including *TDP-43* aggregation. We believe that increasing the master quality control machinery for RNA processing, NMD, in motor neurons may improve the ability of motor neurons to survive in ALS.

We have designed a viral vector product candidate, AAV-UPF1, with the aim of increasing *UPF1* expression in the motor neurons of ALS patients. In preclinical studies, we observed that administration of AAV-UPF1 reduced motor neuron death thought to be driven by the toxic effects of several different genetic causes of ALS including, TDP-43, FUS and C9*orf*72. Improvements in ALS-like symptoms related to limb strength and mobility in rodent models of ALS have also been observed following administration of AAV-UPF1.

We believe that gene therapy using AAV-UPF1 may increase *UPF1* levels in cells affected by ALS, and we intend to deliver our viral vector product candidate to the central nervous system via intrathecal injection, or injection into the spinal canal. We are currently conducting IND enabling studies in animal models and have observed the preservation of neurons and a positive impact on functional endpoints in Fus and TDP-43 neuronal cell cultures. Data is expected to become available on studies regarding modes of central nervous system delivery in non-human primates during 2018 and head-to-head non-human primates capsid study is set to launch during the second half of 2018. In the second half of 2018 we anticipate initiating manufacturing for our ALS program and engaging the FDA in pre-IND discussions, with the goal of filing an IND and initiating a clinical trial of AAV-UPF1 in ALS patients in 2019.

#### Alzheimer's Disease

Disease Background and Market Opportunity

With the world population aging, Alzheimer's disease has emerged as an extremely common and costly disease. While some treatments that have temporary effects on Alzheimer's disease symptoms are available, there is currently no approved treatment that halts the progression of the disease. Two biological pathways have been identified that are considered causes of Alzheimer's disease. They are identified as causative because mutations in genes that affect these pathways alone cause patients to develop the disease. The first causative pathway, identified in rare forms of early onset Alzheimer's disease, is the misprocessing of amyloid precursor protein, or APP, caused by genetic defects in *APP* itself and the APP processing proteins presenilin 1 and 2. The second causative pathway is related to the correct movement, or trafficking, of cellular protein which is controlled by a cell component called the endosome. Loss of function mutations in the endosomal protein sortilin-related receptor 1, or *SORL1*, have recently been shown to cause Alzheimer's disease.

The endosome is an organelle within the cell that is responsible for correctly directing protein trafficking to different sites within the cell as well as to the cell surface. In neurons, there is significant protein trafficking, particularly at dendrites or neuronal connections where the endosomal trafficking system regulates the movement of the cell signaling machinery that allows neurons to communicate with one another.

The molecular machine that drives endosomal protein trafficking is made up of a complex of proteins together called the retromer. The protein encoded by the Alzheimer's disease causing gene *SORL1* is a retromer component. *SORL1* and other components of the retromer complex are commonly deficient in Alzheimer's disease patients' brains. Defects in the endosomal trafficking pathway have also been implicated in other neurodegenerative diseases, including Parkinson's disease, ALS and frontotemporal dementia.

Our Gene Therapy Approach

Our Alzheimer's disease program focuses on the endosomal trafficking pathway. In preclinical studies, we observed that increasing levels of key retromer proteins may reverse endosomal trafficking defects. We are identifying suitable retromer targets for gene augmentation in pre-symptomatic Alzheimer's patients.

There are several reasons why gene therapy is, in principle, well suited for Alzheimer's disease and other neurodegenerative diseases. The first relates to the pathophysiology, time course, and anatomical spread of these disorders. Neurodegenerative diseases generally begin locally in selectively vulnerable regions with "cell sickness" years before rampant cell death and wide-spread anatomical distribution. To be most effective, we believe interventions should be administrated early and will benefit from local delivery. Even then, however, an intervention must maintain its efficacy for years because, unlike other cells in the body, neurons do not typically divide over the course of their life. We believe AAV-delivered gene therapy products may have a durable effect. In the best case scenario, one delivery successfully taken up by targeted neurons would be sufficient for years of efficacy.

An important component of our approach is the development and validation of surrogate markers of endosomal dysfunction and predictive markers of Alzheimer's disease. In particular, several well studied biomarkers linked to Alzheimer's disease, such as amyloid-beta and tau, have also been shown to be biomarkers of endosomal trafficking dysfunction in neurons. Such biomarkers could potentially be used to identify patients with Alzheimer's disease, as well as demonstrate potential product efficacy in the absence of Alzheimer's disease symptoms. By targeting endosomal trafficking dysregulation we aim to address the underlying cause of Alzheimer's disease as well as other neurodegenerative diseases, such as certain forms of Parkinson's disease.

## **Our Gene Regulation Platform**

We are developing a potentially transformative technology designed to enable us to use small molecules to turn gene therapy product candidates on and off. The aim of this gene regulation platform is to transform gene therapy into a generalizable mechanism for the delivery of biologic drugs. The idea is that the gene encoding a particular biologic drug, for example epoetin alfa, or a therapeutic antibody, would be delivered to target cells in the body, but these genes would only be activated in the presence of a specific small molecule. The therapeutic protein would be manufactured by the body only in the presence of the small molecule so that intermittent production of the therapeutic protein would be achieved by dosing with the small molecule drug.

This temporal regulation of gene therapy products by exogenous small molecules has long been a goal of gene therapy researchers. The ability to regulate transgenes by introducing temporal control has the potential to transform the gene therapy landscape and the biologics industry as a whole. Our approach focuses on riboswitches to regulate gene expression rather than on the modulation of transcription factor activity, and this is the basis of our gene regulation platform.

Riboswitches are pieces of RNA that fold into alternative shapes depending on the binding of a specific small molecule to that RNA sequence. One RNA shape allows the gene containing the riboswitch to be active, while the alternative shape inactivates the gene. Riboswitches are used extensively by bacteria, but none have been identified in mammalian cells to date.

We designed a *de-novo* mammalian riboswitch that we have observed responds to small molecules and switch genes on and off in mammalian cells. Our riboswitch contains a stretch of RNA sequence, called an

aptamer, that binds to a specific small molecule. The riboswitch is inserted into the therapeutic transgene cDNA. In the absence of the specific small molecule, the unbound riboswitch folds into the shape that drives the destruction of the entire RNA message and no therapeutic protein is produced in the absence of the small molecule. However, when the small molecule is present and binds to the riboswitch it adopts the alternative RNA shape, causing stable messages to be formed and the therapeutic protein to be produced.

One of the features of our mammalian riboswitch is its range of regulation. Using a small molecule we were able to switch the riboswitch containing gene on to levels greater than 1,000x higher than in the absence of the small molecule. We believe this technology is viable for a therapeutic product and is also the first instance of a proprietary system for screening randomized aptamers and small molecules within mammalian cells for functional interactions.

### **Our Manufacturing Capabilities**

We recently completed our cGMP manufacturing facility situated in London, United Kingdom. Supporting our global approach to clinical development and market supply, we designed the 29,000 square foot facility to meet multiple regulatory standards, including the Medicines and Health Products Regulatory Agency, or MHRA, in the UK, EMA and FDA standards. We recently had our final MHRA certification inspection. In May 2018, we were granted a license to manufacture gene therapy product candidates in our cGMP compliant manufacturing facility by the UK Medicines and Healthcare products Regulatory Agency.

We believe our facility can supply all of our current clinical and preclinical programs through regulatory approval and, should they be approved, provide sufficient capacity, for commercial production. Strategically, we believe our facility will minimize our dependence on third-party CMOs, which we believe provides a significant strategic, clinical and commercial advantage.

Our facility is flexible and scalable, with eleven independent air handling units, two cell culture suites and three separate viral vector production suites, which allows us to produce multiple product candidates in parallel, as well as sequentially at different scales. This allows us to accommodate up to three independent parallel manufacturing streams of viral products that are isolated within dedicated production areas.

Our manufacturing facility includes an integrated analytical department and in-house analytical tool kit that allows for in-house release of clinical and commercial manufactured products. Equipped with dedicated areas for microbiology, molecular biology, and cell-based analytics. Our analytical department can perform product related assays, allowing us to retain and gain expertise that is normally lost to third parties. The close integration allows for rapid turnaround and flexibility in scheduling of key assays, reducing lead times for product candidate releases. Further, our dedicated product fill and finish suite allows us to manufacture a full range of clinical and commercial products under one roof and in our control.

We have more than 40 highly trained multidisciplinary staff on our manufacturing team with backgrounds in manufacturing, managing and delivering gene therapy products.

We have identified and licensed a proprietary HEK293 cell line that is well characterized and that we have banked in 400 vials. The specific cell line, size of the bank, culture media, and cryopreservation agents have been selected to facilitate bridging between process development platforms and targets. Our HEK-293 cells lack the T antigen component and are suitable for both the current adherent culture platform and the bioreactor process. We believe the ability to use the same cell line throughout the product and process development lifecycle will allow us to use a bracketed approach to process validation and comparability, which we believe may reduce the time and costs related to their implementation.

## Competition

The biotechnology and pharmaceutical industries are characterized by rapidly changing technologies, significant competition and a strong emphasis on intellectual property. This is true in the field of gene therapy

generally, and in the treatments for our key disease areas. While we believe that the strength of our team, gene therapy expertise, scientific knowledge and intellectual property provide us with competitive advantages, we face competition from several sources, including large and small biopharmaceutical companies, academic research institutions, government agencies and public and private research institutions. Not only must we compete with other companies that are focused on gene therapy, but any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future.

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, clinical trials, regulatory approvals and product marketing than we do. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials and acquiring technologies complementary to, or necessary for, clinical programs. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

There are other organizations working to improve existing therapies or to develop new therapies for our initially selected disease indications. Depending on how successful these efforts are, it is possible they may increase the barriers to adoption and success for our product candidates, if approved. These efforts include two product candidates Applied Genetic Technologies Corporation, or AGTC, have in Phase 1/2 clinical trials to treat ACHM related to *CNGB3* and *CNGA3*, respectively, a product candidate in Phase 1/2 clinical trials by Nightstar Therapeutics plc and a program AGTC is running to treat XLRP, as well as Luxturna, which is marketed by Spark Therapeutics, Inc. and has been approved to treat *RPE65*-deficiency. We are not aware of any other gene therapy product candidates in clinical development targeting xerostomia. We are aware of other ALS gene therapies utilizing different treatment mechanisms to treat different genetically defined subsets of ALS patients.

We anticipate that we will face intense and increasing competition as new drugs enter the market and advanced technologies become available. We expect any treatments that we develop and commercialize to compete on the basis of, among other things, efficacy, safety, convenience of administration and delivery, price, the level of generic competition and the availability of reimbursement from government and other third-party payors.

#### **Intellectual Property**

Our success depends in large part upon our ability to secure and maintain proprietary protection for our technologies and products and to operate without infringing the proprietary rights of others. Our policy is to protect our proprietary position by, among other methods, filing or collaborating with our licensors to file U.S. and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development and implementation of our business. We also use other forms of protection, such as confidential information and trademark protection, particularly where we do not believe patent protection is appropriate or obtainable. Our patent portfolio consists of a combination of issued patents and pending patent applications that are owned or licensed from third parties.

As of April 30, 2018, we own, have an exclusive license or co-exclusive license under, or an exclusive option to license 27 United States and foreign issued patents and 93 patent applications, pending in the United States and internationally. For any individual patent, the term depends on the applicable law in the country in which the patent is granted. In most countries where we have filed patent applications or in-licensed patents and patent applications, patents have a term of 20 years from the application filing date or earliest claimed non-provisional priority date. In the United States, the patent term is 20 years but may be shortened if a patent is terminally disclaimed over another patent that expires earlier. The term of a U.S. patent may also be lengthened by a patent term adjustment, in order to address administrative delays by the United States Patent and Trademark Office in granting a patent. In the United States, the term of a patent that covers an FDA-approved drug or biologic may be

eligible for patent term extension in order to restore the period of a patent term lost during the premarket FDA regulatory review process. The Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, permits a patent term extension of up to five years beyond the natural expiration of the patent. The patent term restoration period is generally equal to the regulatory review period for the approved product which period occurs after the date the patent issued, subject to certain exceptions. Only one patent may be extended for a regulatory review period for any product, and the application for the extension must be submitted prior to the expiration of the patent. In the future, we may decide to apply for restoration of patent term for one of our currently owned or licensed patents to extend its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant BLA.

## Company-Owned Intellectual Property

We own six patent families relating to gene regulation platform technologies developed by us. The first patent family, includes 21 pending patent applications with claims directed to compositions of matter and methods of use in the United States, Europe, Australia, Canada, China, India, Japan, Brazil, Egypt, Indonesia, Israel, Republic of Korea, Malaysia, Mexico, New Zealand, Vietnam, African Regional IPO, Philippines, Singapore, South Africa and Eurasia. Patents issued from this family are expected to expire February 2, 2036, not including any patent term adjustments that may extend the patent term in certain jurisdictions. The other five families include five international applications relating to different gene regulations platform technologies with claims directed to compositions of matter and methods of use. We expect to convert each of these international applications to U.S. and international patent filings in due course. Patents issued from these five patent families are expected to expire in 2037 and 2038, not including any patent term adjustments that may extend the patent term in certain jurisdictions.

#### Licensed Intellectual Property

Certain of our issued patents and pending patent applications are exclusively licensed to us from UCLB and Brandeis.

**UCLB** 

The UCLB portfolio includes three licensed patent families relating to our *RPE65*, *CNGA3*, and *RPGR* gene therapy programs and one optioned patent family relating to our dry AMD gene therapy program with a combined 46 pending patent applications.

The first patent family, with claims directed to compositions of matter and methods of use relating to our *RPE65* program, and the AAV-RPE65 product candidate includes 17 pending patent applications in the United States, Europe, Australia, Canada, China, India, Japan, Brazil, Egypt, Israel, Malaysia, Mexico, New Zealand, Nigeria, Philippines, Singapore, and Thailand. Patents issued from this family are expected to expire February 8, 2036, not including any patent term extensions or adjustments that may extend the patent term in certain jurisdictions.

The second patent family, with claims directed to compositions of matter and methods of use relating to our achromatopsia program and the AAV-CNGA3 product candidate, includes one pending patent application, which we expect to convert to an international application and subsequent U.S. and international patent filings in due course. Patents issued from this family are expected to expire in 2039, not including any patent term extensions or adjustments that may extend the patent term in certain jurisdictions.

The third patent family, with claims directed to compositions of matter and methods of use relating to our retinitis pigmentosa program and the AAV-RPGR product candidate, includes five pending applications in the United States, Europe, Canada, China, and Japan. Patents issued from this family are expected to expire in July 2035, not including any patent term extensions or adjustments that may extend the patent term in certain jurisdictions.

The fourth patent family which we have optioned, with claims directed to compositions of matter and methods of use relating to our dry AMD gene therapy program, includes 23 pending applications in the United States, Europe, Australia, Canada, China, India, Japan, Brazil, Egypt, Indonesia, Israel, Republic of Korea, Malaysia, Mexico, New Zealand, Nigeria, Vietnam, African Regional IPO, Philippines, Singapore, South Africa, Thailand and Eurasia. Patents issued from this family are expected to expire February 2036, not including any patent term extensions or adjustments that may extend the patent term in certain jurisdictions.

#### **Brandeis**

The licensed Brandeis portfolio includes one patent family with claims directed to compositions of matter and methods of use relating to our ALS gene therapy program and the AAV-UPF1 product candidate. This patent family includes an issued patent in Australia and pending patent applications in the United States, Europe, Canada and Hong Kong. Patents issued from this family are expected to expire October 8, 2033, not including any patent term extensions or adjustments that may extend the patent term in certain jurisdictions.

## **License Agreements**

#### License Agreement between Athena and UCLB

In February 2015, Athena entered into a license agreement with UCLB (the license agreement, together with all applicable amendments, is referred to as the First UCLB License Agreement, and together with all addendums, the First UCLB Agreement). In March 2016, all of Athena's rights, obligations, and liabilities under the First UCLB Agreement and all of its subsequent amendments, supplements, addendums and modifications were novated to us under a deed of novation. Pursuant to the First UCLB Agreement, UCLB granted Athena an exclusive, worldwide, and sublicensable license under certain intellectual property rights controlled by UCLB related to our *RPE65* and *CNGA3* and *CNGB3* gene therapy programs, including certain patent filings with claims directed to compositions of matter and methods of use relating to our *RPE65* program and the AAV-RPE65 product candidate, to develop and commercialize licensed products in the field of ocular gene therapy. We must use diligent efforts to develop and commercialize the licensed products.

In addition, under the terms of the First UCLB Agreement, we have an exclusive option to negotiate and enter into license addendums, or Athena Addendums, pursuant to which we would obtain royalty-bearing licenses under certain additional intellectual property rights, including certain patent filings relating to our dry AMD gene therapy program, on reasonable commercial terms. Such option expires on February 4, 2019.

Under the terms of the First UCLB Agreement, we issued a certain number of our ordinary shares to UCLB in accordance with a certain shareholder's agreement, or the Athena Shareholders' Agreement. We are also required to pay UCLB sales milestone payments of up to a total of £39.75 million in the aggregate and an annual management fee of £50,000 until certain royalty payments have been paid.

Commencing on the first commercial sale of licensed products, we must make low single-digit percentage royalty payments to UCLB on net sales of such products. Our royalty obligations under the agreement continue on a licensed product-by-licensed product and country-by-country basis until the earlier to occur of (a) the expiration of the last valid claim of a patent claiming such licensed product in such country, or (b) the 10th anniversary of the first commercial sale of such licensed product in such country. In addition, we must pay UCLB mid-twenty percentages of certain sublicensing revenues.

Unless terminated earlier, the First UCLB License Agreement will remain in effect until the expiration or termination of the last Athena Addendum. The First UCLB License Agreement may be terminated: (a) by either party in the event of the other party's material breach that remains uncured for 30 days (or for 14 days in the case of breaches related to payment obligations), (b) by UCBL in the event of our material breach of the Athena Shareholders' Agreement that remains uncured for 30 days, (c) by either party for the other party's

insolvency, (d) immediately by UCLB if we challenge the validity or ownership of UCLB's patents, (e) immediately by UCLB if we are in persistent breach of the First UCLB License Agreement and the parties fail to agree upon a mechanism to remedy such persistent breach (or we do not comply with such agreed upon mechanism), (f) immediately by UCLB if we are in material breach of the First UCLB License Agreement more than twice in any 24-month period, even if such breaches have been remedied, or (g) immediately by UCLB if we undergo certain change of control events or if we enter into a sublicense with certain prohibited persons which may adversely affect UCL's and/or UCLB's reputation.

Unless terminated earlier, each Athena Addendum will remain in effect on a country-by-country basis until the expiration of the last payment obligation under the First UCLB Agreement. Each Athena Addendum may be terminated: (a) by either party in the event of the other party's material breach that remains uncured for 30 days (or for 14 days in the case of breaches related to payment obligations), (b) by UCLB if we fail to achieve any of the milestone events in the applicable Athena Addendum within six months after the applicable milestone deadline, (c) immediately by UCLB if we challenge the validity or ownership of UCLB's patents, (d) by UCLB if we fail to provide an updated development plan for the relevant Athena Addendum within six months of the effective date of such Athena Addendum, (e) immediately by UCLB if we are in persistent breach of the relevant Athena Addendum and the parties fail to agree upon a mechanism to remedy such persistent breach (or we do not comply with such agreed upon mechanism), or (f) immediately by UCLB if we are in material breach of the relevant Athena Addendum more than twice in any 24-month period, even if such breaches have been remedied. Each Athena Addendum may also be terminated, or the exclusive licenses granted under the relevant Athena Addendum may be converted to a non-exclusive license, by UCLB upon three-months' notice if we, based on an independent expert determination, fail to use diligent efforts to achieve certain milestone events or to develop and commercially exploit licensed products and do not cure such failure within a certain cure period.

### License Agreements with UCLB

July 2017 Agreement with UCLB

In July 2017, we entered into a license agreement with UCLB, or the Second UCLB Agreement. Pursuant to the Second UCLB Agreement, UCLB granted us an exclusive, worldwide, and sublicensable license under certain intellectual property rights, including certain patent filings, controlled by UCLB with claims directed to compositions of matter and methods of use relating to our retinitis pigmentosa gene therapy program and the AAV-RPGR product candidate to develop and commercialize licensed products in the field of ocular gene therapy. We must use diligent efforts to develop and commercialize the licensed products. Under the terms of the Second UCLB Agreement, we paid an initial upfront payment of \$17,888. We are also required to pay UCLB sales milestone payments of up to a total of £39.75 million in the aggregate and an annual management fee of £50,000 until certain royalty payments have been paid.

Commencing on the first commercial sale of licensed products, we must make low single-digit percentage royalty payments to UCLB on net sales of such products. Our royalty obligations under the agreement continue on a licensed product-by-licensed product and country-by-country basis until the latest to occur of the expiration of the last valid claim of a patent claiming such licensed product in such country, the expiration of regulatory exclusivity for such licensed product in such country, or the 10th anniversary of first commercial sale of such licensed product in such country. The Second UCLB Agreement will remain in effect on a country-by-country basis until the expiration of the last payment obligation in such country. The Second UCLB Agreement may be terminated: (a) by either party in the event of the other party's material breach that remains uncured for 30 days, (b) by either party for the other party's insolvency, or (c) immediately by UCLB if we are in persistent breach of the Second UCLB Agreement and the parties fail to agree upon, within a reasonable amount of time, a mechanism to remedy such persistent breach (or we do not comply with such agreed upon mechanism), or (d) immediately by UCLB if we undergo certain change of control events or if we enter into a sublicense with certain prohibited persons which may adversely affect UCL's and/or UCLB's reputation. The Second UCLB Agreement may also be terminated or converted to a non-exclusive license by UCLB upon three months' notice

if we, based on an independent expert determination, fail to use diligent efforts to develop and commercially exploit licensed products and do not cure such failure within a certain cure period.

March 2018 Agreement with UCLB

In March 2018, we, together with MeiraGTx UK II, entered into a license agreement with UCLB, or the Third UCLB Agreement. As of March 2018, the Third UCLB Agreement supersedes the Athena Agreement regarding the *CNGA3* program. Pursuant to the Third UCLB Agreement, UCLB granted us an exclusive, worldwide, and sublicensable license under certain intellectual property rights controlled by UCLB, including a certain patent filing with claims directed to compositions of matter and methods of use relating to our achromatopsia gene therapy program and the AAV-CNGA3 product candidate to develop and commercialize licensed products in the field of ocular gene therapy. We must use diligent efforts to develop and commercialize the licensed products.

Under the terms of the Third UCLB Agreement, we paid an initial upfront payment of £6,994, and issued certain number of shares with equivalent cash value of £100,000 to UCLB. We are also required to pay UCLB sales milestone payments of up to a total of £39.75 million in the aggregate and an annual management fee of £50,000 until certain royalty payments have been paid.

Commencing on the first commercial sale of licensed products, we must make low single-digit percentage royalty payments to UCLB on net sales of such products. Our royalty obligations under the agreement continue on a licensed product-by-licensed product and country- by-country basis until the latest to occur of the expiration of the last valid claim of a patent claiming such licensed product in such country, the expiration of any regulatory exclusivity for all licensed products in such country, or the tenth anniversary of first commercial sale of such licensed product in such country.

The Third UCLB Agreement will remain in effect on a country-by-country basis until the expiration of the last payment obligation in such country. The Third UCLB Agreement may be terminated: (a) by either party in the event of the other party's material breach that remains uncured for 30 days, (b) by either party for the other party's insolvency, (c) immediately by UCLB if we are in persistent breach of the Third UCLB Agreement and the parties fail to agree upon a mechanism to remedy such persistent breach (or we do not comply with such agreed upon mechanism), (d) immediately by UCLB if we fail to comply with certain obligations relating to the issuance of shares to UCLB under the Third UCLB Agreement, or (e) immediately by UCLB if we undergo certain change of control events or if we enter into a sublicense with certain prohibited persons, which may adversely affect UCL's and/or UCLB's reputation. The Third UCLB Agreement may also be terminated or converted to a non-exclusive license by UCLB upon three months' notice if we, based on an independent expert determination, fail to use diligent efforts to develop and commercially exploit licensed products and do not cure such failure within a certain cure period.

License Agreement between Bri-Alzan Inc. and Brandeis

In May 2013, BRI-Alzan Inc., or BRI-Alzan, entered into a license agreement with Brandeis, or the Brandeis Agreement. On December 31, 2015, we entered into an Agreement and Plan of Merger, or the BRI-Alzan Merger Agreement, with BRI-Alzan, and the Brandeis Agreement was assigned to us as a result of such merger. Pursuant to the terms of the BRI-Alzan Merger Agreement, we agreed to make cash payments to BRI-Alzan upon the achievement of certain milestones, subject to an aggregate cap of \$4,500,000. In addition, we agreed to make low single-digit percentage royalty payments to BRI-Alzan on net sales of any product for the therapeutic or prophylactic treatment of ALS that is covered by a valid claim of the patent rights licensed under the Brandeis Agreement. The BRI-Alzan Merger Agreement includes customary confidentiality, indemnification, non-competition and non-solicitation provisions.

Pursuant to the Brandeis Agreement, Brandeis granted us an exclusive, worldwide license under certain patent rights with claims directed to compositions of matter and methods of use relating to our ALS gene therapy program and the AAV-UPF1 product candidate to develop and commercialize licensed products.

We must use commercially reasonable efforts to develop and commercialize licensed products. We also acquired non-exclusive, worldwide licenses to certain know-how controlled by Brandeis' to exploit licensed products. We are required to pay Brandeis developmental and regulatory milestone payments of up to a total of \$1.0 million in the aggregate. We are also required to pay Brandeis annual license maintenance fees ranging from \$15,000 to \$100,000 depending on the development stage of the licensed product. Commencing on the first commercial sale of licensed products, we must make low single-digit percentage royalty payments to Brandeis on net sales of such products. In addition, we must pay Brandeis mid-teen percentages of sublicensing revenues.

The Brandeis Agreement will remain in effect on a country-by-country basis until the earlier of: (a) 1 year after the date that we, our affiliates or sublicensees last sell any licensed product in such country or (b) until the expiration of the last—to-expire of the licensed patent rights in such country. The Brandeis Agreement may be terminated by Brandeis for our insolvency or for our material breach that remains uncured for 60 days (or for 30 days in the case of breaches related to payment obligations). Such material breach may be cured only once in any 12-month period. Brandeis may also terminate any license granted under the Brandeis Agreement if we fail to timely achieve certain regulatory milestone events.

#### **Trade Secrets**

We also rely on trade secrets, technical know-how and continuing innovation to develop and maintain our competitive advantage. Our policy requires inventors who are identified on any company-owned patent applications to assign rights to us. We also rely on confidentiality agreements with our employees, consultants and other advisors to protect our proprietary information. Our policy is to require third parties that receive material confidential information to enter into confidentiality agreements with us.

#### **Trademarks**

Our trademark MeiraGTx has been registered in the European Union and a U.S. application is pending.

#### **Government Regulation and Product Approval**

Governmental authorities in the U.S., at the federal, state and local level, and other countries extensively regulate, among other things, the research, development, testing, manufacture, labeling, packaging, promotion, storage, advertising, distribution, marketing, post-approval monitoring and reporting and export and import of products such as those we are developing. The processes for obtaining regulatory approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, are extensive and require the expenditure of substantial time and financial resources.

#### **FDA Approval Process**

We expect our future product candidates to be regulated as biologics. Biological products, including gene therapy products, are subject to extensive regulation by the FDA under the Federal Food, Drug, and Cosmetic Act, or FDCA, and the Public Health Service Act, or PHSA, and other federal, state, local and foreign statutes and regulations. Both the FDCA and the PHSA and their corresponding regulations govern, among other things, the research, development, safety, testing, packaging, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of biological products. Before clinical testing of biological products in the United States may begin, we must submit an investigational new drug application, or IND, to the FDA, which reviews the clinical protocol, and the IND must become effective before clinical trials may begin. In some instances, we must also submit our protocols to the National Institutes of Health, or NIH, through its Recombinant DNA Advisory Committee, or RAC, for review before initiating clinical testing of gene therapy products.

Gene therapy products must be approved by the FDA before they may be legally marketed in the United States and by the appropriate foreign regulatory agencies before they may be legally marketed in foreign countries. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources and we may not be able to obtain the required regulatory approvals.

Within the FDA, the Center for Biologics Evaluation and Research, or CBER, regulates gene therapy products. The CBER works closely with the NIH and its RAC, which makes recommendations to the NIH on gene therapy issues and engages in a public discussion of scientific, safety, ethical and societal issues related to proposed and ongoing gene therapy protocols. The FDA has published guidance documents with respect to the development and submission of gene therapy protocols. The FDA also has published guidance documents related to, among other things, gene therapy products in general, their preclinical assessment, observing subjects involved in gene therapy clinical trials for delayed adverse events, potency testing, and chemistry, manufacturing and control information in gene therapy INDs.

To date, the FDA has approved three human gene therapy products for sale, including Kite Pharma's Yescarta, Novartis' Kymriah and Spark's Luxturna, and has provided general guidance regarding the development of gene therapy products. For example, the FDA has established the Office of Tissue and Advanced Therapies within CBER, to consolidate the review of gene therapy and related products, and the Cellular, Tissue and Gene Therapies Advisory Committee, to advise CBER on its reviews. In addition, the FDA has issued a growing body of clinical guidelines, chemical, manufacturing and control, or CMC, guidelines and other guidelines, all of which are intended to facilitate industry's development of gene therapy products.

Ethical, social and legal concerns about gene-editing technology, gene therapy, genetic testing and genetic research could result in additional regulations restricting or prohibiting the processes we may use. Federal and state agencies, congressional committees and foreign governments have expressed interest in further regulating biotechnology. More restrictive regulations or claims that our products are unsafe or pose a hazard could prevent us from commercializing any product candidates. New government requirements may be established that could delay or prevent regulatory approval of our product candidates under development. It is impossible to predict whether legislative changes will be enacted, regulations, policies or guidance changed, or interpretations by agencies or courts changed, or what the impact of such changes, if any, may be.

# U.S. Biological Products Development Process

The FDA determined that more than minimally manipulated products must be approved by the FDA through the Biologics License Application, or BLA, process before they may be legally marketed in the United States. The process required by the FDA before a biologic may be marketed in the United States generally involves the following:

- completion of extensive nonclinical, sometimes referred to as preclinical laboratory tests, and preclinical studies and applicable
  requirements for the humane use of laboratory animals and formulation studies in accordance with applicable regulations, including
  good laboratory practices, or GLPs;
- submission to the FDA of an IND application, which must become effective before clinical trials may begin;
- approval by an independent Institutional Review Board, or IRB, or ethics committee at each clinical site before the trial is commenced;
- performance of adequate and well controlled human clinical trials according to the FDA's regulations commonly referred to as good clinical practices, or GCPs, and any additional requirements for the protection of human research subjects and their health information, to establish the safety and efficacy of the proposed biological product for its intended use;

- submission to the FDA of a BLA for marketing approval that includes substantive evidence of safety, purity, potency and efficacy from results of nonclinical testing and clinical trials;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the biological product is produced to assess compliance with cGMP to assure that the facilities, methods and controls are adequate to preserve the biological product's identity, strength, quality and purity;
- · potential FDA audit of the nonclinical and clinical study sites that generated the data in support of the BLA; and
- FDA review and approval, or licensure, of the BLA.

Before testing any biological product candidate, including a gene therapy product, in humans, the product candidate enters the preclinical testing stage. Preclinical tests, also referred to as nonclinical studies, include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the product candidate. The conduct of the preclinical tests must comply with federal regulations and requirements, including GLPs. The clinical trial sponsor must submit the results of the preclinical tests, together with manufacturing and controls, information about product chemistry, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. Some preclinical testing, such as reproductive toxicity tests and carcinogenicity in animals, may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, after which human clinical trials may begin unless the FDA places the clinical trial on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. With gene therapy protocols, if the FDA allows the IND to proceed, but a RAC decides that full public review of the protocol is warranted, the FDA will request at the completion of its IND review that sponsors delay initiation of the protocol until after completion of the RAC review process. The FDA may also impose clinical holds on a biological product candidate at any time before or during clinical trials due to safety concerns or non-compliance. If the FDA imposes a clinical hold, trials may not recommence without FDA authorization and then only under terms authorized by the FDA. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate such trials. In addition to the IND submission process, sponsors of certain clinical trials of cells containing recombinant or synthetic nucleic acid molecules, including human gene transfer studies, must comply with the NIH's Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, or NIH Guidelines. The NIH Guidelines set forth the principles and requirements for NIH and institutional oversight of research with recombinant or synthetic nucleic acid molecules, including the standards for investigators and institutions to follow to ensure the safe handling and containment of such molecules. In April 2016, modifications to the NIH Guidelines went into effect, pursuant to which only a subset of human gene transfer protocols are subject to review by the RAC. Specifically, under the modified NIH Guidelines, RAC review of the protocol will be required only in exceptional cases where an oversight body such as an Institutional Biosafety Committee, or IBC, which provides local review and oversight of research utilizing recombinant or synthetic nucleic acid molecules, or an IRB determines that the protocol would significantly benefit from RAC review, and the protocol (a) uses a new vector, genetic material, or delivery methodology that represents a first-in-human experience and thus presents an unknown risk, and/or (b) relies on preclinical safety data that were obtained using a new preclinical model system of unknown and unconfirmed value, and/or (c) involves a proposed vector, gene construct, or method of delivery associated with possible toxicities that are not widely known and that may render it difficult for oversight bodies to evaluate the protocol rigorously. The RAC review proceedings are public, and reports are posted publicly to the website for the NIH's Office of Biotechnology Activities. Although compliance with the NIH Guidelines is mandatory for research conducted at or sponsored by institutions receiving NIH funding of recombinant or synthetic nucleic acid molecule research, many companies and other institutions not otherwise subject to the NIH Guidelines voluntarily follow them. Independent of RAC review, the NIH Guidelines also require all human gene transfer protocols subject to the NIH Guidelines to be registered

with NIH, with limited exemptions. A study subject to the NIH Guidelines may not begin until the IBC approves the protocol, and the IBC cannot approve the protocol until confirmation from the NIH that such registration is complete. In the event that RAC review is warranted, the protocol registration process cannot be completed until RAC review has taken place.

Clinical trials involve the administration of the biological product candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the study sponsor's control. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, the efficacy measurements to be evaluated and the parameters to be used to monitor subject safety, including stopping rules that assure a clinical trial will be stopped if certain adverse events should occur. Each protocol and any amendments to the protocol must be submitted to the FDA as part of the IND. Clinical trials must be conducted and monitored in accordance with the FDA's regulations comprising the GCP requirements, including the requirement that all research subjects provide informed consent. Further, each clinical trial must be reviewed and approved by an independent institutional review board, or IRB, at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of study participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the form and content of the informed consent that must be signed by each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. Clinical trials also must be reviewed by an IBC, a local institutional committee that reviews and oversees basic and clinical research conducted at that institution. The IBC assesses the safety of the research and identifies any potential risk to public health or the environment.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1. The biological product candidate is initially introduced into healthy human subjects and tested for safety. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.
- Phase 2. The biological product candidate is evaluated in a limited patient population to identify possible adverse effects and safety
  risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal
  dosage and dosing schedule.
- Phase 3. Clinical trials are undertaken to further evaluate dosage, clinical efficacy, potency, and safety in an expanded patient
  population at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of
  the product and provide an adequate basis for product labeling.

In most cases, the FDA requires two adequate and well controlled Phase 3 clinical trials to demonstrate the safety and efficacy of a biological product. In rare instances, a single Phase 3 trial, together with other confirmatory evidence may be sufficient to support a BLA submission. Post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These clinical trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up. The FDA recommends that sponsors observe subjects for potential gene therapy-related delayed adverse events for a 15-year period, including a minimum of five years of annual examinations followed by ten years of annual queries, either in person or by questionnaire.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data, and clinical trial investigators. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA. Written IND safety reports must be promptly

submitted to the FDA, the NIH and the investigators for serious and unexpected adverse events, any findings from other trials, tests in laboratory animals or *in vitro* testing that suggest a significant risk for human subjects, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor or its data safety monitoring board may suspend or permanently discontinue a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk or the clinical trial is not being conducted in accordance with FDA regulations. Similarly, an IRB can suspend or terminate approval of a clinical study at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the biological product candidate has been associated with unexpected serious harm to patients. The FDA and the IRB may also halt, terminate or impose other conditions if either believes the patients are subject to unacceptable risk.

There are also requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries. Sponsors of clinical trials of FDA-regulated products, including biologics, are required to register and disclose certain clinical trial information, which is publicly available at www.clinicaltrials.gov. Information related to the product, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed until the new product or new indication being studied has been approved.

Human gene therapy products based on gene-editing technology are a new category of therapeutics. Because this is a relatively new and expanding area of novel therapeutic interventions, there can be no assurance as to the length of the study period, the number of patients the FDA will require to be enrolled in the trials in order to establish the safety, efficacy, purity and potency of human gene therapy products, or that the data generated in these trials will be acceptable to the FDA to support marketing approval. The NIH and the FDA have a publicly accessible database, the Genetic Modification Clinical Research Information System, which includes information on gene transfer trials and serves as an electronic tool to facilitate the reporting and analysis of adverse events in these trials.

Concurrent with clinical trials, companies usually complete additional animal trials and must also develop additional information about the physical characteristics of the biological product candidate as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. To help reduce the risk of the introduction of adventitious agents with use of biological products, the PHS Act emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the sponsor must develop methods for testing the identity, strength, quality, potency and purity of the final biological product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the biological product candidate does not undergo unacceptable deterioration over its shelf life.

# U.S. Review and Approval Processes

After the completion of clinical trials of a biological product candidate, FDA approval of a BLA must be obtained before commercial marketing and distribution of the biological product. The BLA must include results of product development, laboratory and animal trials, human trials, information on the manufacture, pharmacology, chemistry and controls of the product, proposed labeling and other relevant information. In addition, under the Pediatric Research Equity Act, or PREA, a BLA or supplement to a BLA must contain data to assess the safety and effectiveness of the biological product candidate for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective.

The Food and Drug Administration Safety and Innovation Act, or FDASIA, requires that a sponsor who is planning to submit a marketing application for a drug or biological product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial Pediatric Study Plan, or PSP, within sixty days after an end-of-Phase 2 meeting or as may be agreed between the sponsor and FDA. The initial PSP must include, among other things, an outline of the pediatric study or studies that the sponsor plans to conduct, including to the extent practicable study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information, along with any other information specified in FDA regulations. The FDA and the sponsor must reach agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from nonclinical studies, early phase clinical trials, and/or other clinical development programs. The FDA may grant deferrals for submission of data or full or partial waivers. Unless otherwise required by regulation, PREA does not apply to any biological product for an indication for which orphan designation has been granted. The testing and approval processes require substantial time and effort and there can be no assurance that the FDA will accept the BLA for filing and, even if filed, that any approval will be granted on a timely basis, if at all.

Under the Prescription Drug User Fee Act, or PDUFA, as amended, each BLA must be accompanied by a user fee. The FDA adjusts the PDUFA user fees on an annual basis. PDUFA also imposes an annual program fee for products. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first human drug application filed by a small business. Additionally, no user fees are assessed on BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

Within 60 days following submission of the application, the FDA reviews a BLA submitted to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the BLA. Under PDUFA, the FDA has agreed to certain performance goals to complete the review of BLAs. The FDA may give a priority review designation to biological products that offer major advances in treatment, or provide a treatment where no adequate therapy exists. A priority review means that the goal for the FDA to review an application is six months, rather than the standard review of ten months under current PDUFA guidelines. Under the current PDUFA agreement, these six and ten month review periods are measured from the "filing" date rather than the receipt date for original BLAs, which typically adds approximately two months to the timeline for review and decision from the date of submission.

The FDA reviews the BLA to determine, among other things, whether the proposed product is safe and potent, or effective, for its intended use, and has an acceptable purity profile, and whether the product is being manufactured in accordance with cGMP requirements to assure and preserve the product's identity, safety, strength, quality, potency and purity. The FDA may refer applications for novel biological products or biological products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. During the biological product approval process, the FDA also will determine whether a Risk Evaluation and Mitigation Strategy, or REMS, is necessary to assure the safe use of the biological product candidate. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS; the FDA will not approve the BLA without a REMS, if required.

Before approving a BLA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in

compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure that the clinical trials were conducted in compliance with IND study requirements and GCP requirements. To assure cGMP and GCP compliance, an applicant must incur significant expenditure of time, money and effort in the areas of training, record keeping, production, and quality control.

Notwithstanding the submission of relevant data and information, the FDA may ultimately decide that the BLA does not satisfy its regulatory criteria for approval and deny approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data. If the agency decides not to approve the BLA in its present form, the FDA will issue a complete response letter that usually describes all of the specific deficiencies in the BLA identified by the FDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the BLA, the FDA will issue an approval letter. Under the current PDUFA guidelines, the FDA has committed to reviewing such resubmissions in two or six months of receipt depending on the type of information included.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the BLA with REMS, to ensure the benefits of the product outweigh its potential risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a medicine and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. The requirement for a REMS can materially affect the potential market and profitability of the product.

Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. Changes to some of the conditions established in an approved BLA, including changes in indications, product labeling, manufacturing processes or facilities, require submission and FDA approval of a new BLA or BLA supplement before the change can be implemented. A BLA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing BLA supplements as it does in reviewing BLAs. The FDA may require one or more Phase 4 post-market studies or surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies.

Additionally, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could impact the timeline for regulatory approval or otherwise impact ongoing development programs. For example, in December 2016, the 21st Century Cures Act was signed into law. This act is intended, among other things, to modernize the regulation of drugs and biologics and to spur innovation, and contains provisions specific to the development of cell therapies.

One of the performance goals agreed to by the FDA under the PDUFA is to review 90% of standard BLAs in ten months from the filing date and 90% of priority BLAs in six months from the filing date, whereupon a review decision is to be made. The FDA does not always meet its PDUFA goal dates for standard and priority BLAs and its review goals are subject to change from time to time. The review process and the PDUFA goal date may be extended by three months if the FDA requests or the BLA sponsor otherwise provides additional information or clarification regarding information already provided in the submission within the last three months before the PDUFA goal date.

### Orphan Drug Designation

The FDA may grant Orphan drug designation to drugs or biologics intended to treat a rare disease or condition that affects fewer than 200,000 individuals in the United States, or if it affects more than 200,000 individuals in the United States, there is no reasonable expectation that the cost of developing and marketing the drug or biologic for this type of disease or condition will be recovered from its sales in the United States. Orphan drug designation must be requested before submitting a BLA. After the FDA grants orphan product designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

In the United States, Orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and BLA user-fee waivers. In addition, if a product receives the first FDA approval for the indication for which it has orphan designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application, including a full BLA, to market the same drug or biologic for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity or where the manufacturer with orphan exclusivity is unable to assure sufficient quantities of the approved orphan-designated product. Competitors, however, may receive approval of different products for the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity. Orphan product exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval of the same biological product as defined by the FDA or if our product candidate is determined to be contained within the competitor's product for the same indication or disease. If a drug or biological product designated as an orphan product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan product exclusivity. In addition, exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

#### **Expedited Development and Review Programs**

The FDA has a Fast Track program that is intended to expedite or facilitate the process for reviewing new biological products that meet certain criteria. Specifically, new biological products are eligible for Fast Track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a new biologic may request that the FDA designate the biologic as a Fast Track product at any time during the clinical development of the product. The FDA must determine if the biologic product candidate qualifies for Fast Track designation within 60 days of receipt of the sponsor's request. Unique to a Fast Track product, the FDA may consider for review sections of the marketing application on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the application, the FDA agrees to accept sections of the application and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application.

Any product submitted to the FDA for marketing, including under a Fast Track program, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. Any product is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis or prevention of a disease compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new biological product designated for priority review in an effort to facilitate the review. Additionally, a product may be eligible for accelerated approval. Biological products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide

meaningful therapeutic benefit over existing treatments may be eligible for accelerated approval, which means that they may be approved on the basis of adequate and well controlled clinical trials establishing that the product has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a biological product subject to accelerated approval perform adequate and well-controlled post-marketing Phase 4 clinical trials. Failure to conduct required post-approval trials, or to confirm a clinical benefit during post-marketing trials, will allow the FDA to withdraw the approved biologic product from the market on an expedited basis. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. Fast Track designation, priority review and accelerated approval do not change the standards for approval but may expedite the development or approval process.

In addition, under the provisions of FDASIA, enacted in 2012, the FDA established a Breakthrough Therapy Designation which is intended to expedite the development and review of products that treat serious or life-threatening diseases or conditions. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the features of Fast Track designation, as well as more intensive FDA interaction and guidance. The Breakthrough Therapy Designation is a distinct status from both accelerated approval and priority review, but these can also be granted to the same product candidate if the relevant criteria are met. The FDA must take certain actions, such as holding timely meetings and providing advice, intended to expedite the development and review of an application for approval of a breakthrough therapy. All requests for breakthrough therapy designation will be reviewed within 60 days of receipt, and FDA will either grant or deny the request.

Furthermore, as part of its implementation of the 21st Century Cures Act, the FDA established the Regenerative Medicine Advanced Therapy, or RMAT, designation, to facilitate an efficient development program for, and expedite review of, certain drugs and biological products. A biological product is eligible for RMAT designation if it qualifies as a RMAT, which is defined as a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any combination product using such therapies or products, with limited exceptions, and is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition and for which preliminary clinical evidence indicates that the biological product has the potential to address unmet medical needs for such a disease or condition. Like breakthrough therapy designation, RMAT designation provides potential benefits that include more frequent meetings with FDA to discuss the development plan for the product candidate, and eligibility for rolling review and priority review. Products granted RMAT designation may also be eligible for accelerated approval on the basis of a surrogate or intermediate endpoint reasonably likely to predict long-term clinical benefit, or reliance upon data obtained from a meaningful number of sites, including through expansion to additional sites. RMAT-designated products that receive accelerated approval may, as appropriate, fulfill their post-approval requirements through the submission of clinical evidence, clinical trials, patient registries, or other sources of real world evidence (such as electronic health records); through the collection of larger confirmatory data sets; or via post-approval monitoring of all patients treated with such therapy prior to approval of the therapy.

Fast Track designation, priority review, accelerated approval, breakthrough therapy designation and RMAT designation do not change the standards for approval but may expedite the development or approval process. Even if we receive one of these designations for our product candidates, the FDA may later decide that our product candidates no longer meets the conditions for qualification. In addition, receiving these designations may not provide us with a material commercial advantage.

### Post-Approval Requirements

Maintaining substantial compliance with applicable federal, state, and local statutes and regulations requires the expenditure of substantial time and financial resources. Rigorous and extensive FDA regulation of biological products continues after approval, particularly with respect to cGMP requirements. We will rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of any products that we may commercialize. Manufacturers of our products are required to comply with applicable requirements in the cGMP regulations, including quality control and quality assurance and maintenance of records and documentation. Other post-approval requirements applicable to biological products, include reporting of cGMP deviations that may affect the identity, potency, purity and overall safety of a distributed product, record-keeping requirements, reporting of adverse effects, reporting updated safety and efficacy information, and complying with electronic record and signature requirements.

After a BLA is approved, the product also may be subject to official lot release. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot. The FDA also may perform certain confirmatory tests on lots of some products, such as viral vaccines, before releasing the lots for distribution by the manufacturer. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency, and effectiveness of biological products.

To help reduce the increased risk of the introduction of adventitious agents, the PHSA Act emphasizes the importance of manufacturing controls for products whose attributes cannot be precisely defined. The PHSA Act also provides authority to the FDA to immediately suspend biologics licenses in situations where there exists a danger to public health, to prepare or procure products in the event of shortages and critical public health needs, and to authorize the creation and enforcement of regulations to prevent the introduction or spread of communicable diseases within the United States.

The FDA may require one or more Phase 4 post-market trials or surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies. We also must comply with the FDA's advertising and promotion requirements, such as those related to direct-to-consumer advertising, the prohibition on promoting products for uses or in patient populations that are not described in the product's approved labeling (known as "off-label use"), industry-sponsored scientific and educational activities, and promotional activities involving the internet. Biologics may be marketed only for the approved indications and in accordance with the provisions of the approved labeling.

Discovery of previously unknown problems or the failure to comply with the applicable regulatory requirements may result in restrictions on the marketing of a product or withdrawal of the product from the market as well as possible civil or criminal sanctions. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant or manufacturer to administrative or judicial civil or criminal sanctions and adverse publicity. FDA sanctions could include refusal to approve pending applications, withdrawal of an approval, clinical hold, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, mandated corrective advertising or communications with doctors, debarment, restitution, disgorgement of profits, or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

Biological product manufacturers and other entities involved in the manufacture and distribution of approved biological products are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for

compliance with cGMP requirements and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved BLA, including withdrawal of the product from the market. In addition, changes to the manufacturing process or facility generally require prior FDA approval before being implemented and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

#### U.S. Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of the FDA approval of the use of our product candidates, some of our U.S. patents may be eligible for limited patent term extension under Hatch-Waxman Act. The Hatch-Waxman Act permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally equal to the regulatory review period for the approved product which period occurs after the date the patent issued, subject to certain exceptions. Only one patent may be extended for a regulatory review period for any product, and the application for the extension must be submitted prior to the expiration of the patent. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may intend to apply for restoration of patent term for one of our currently owned or licensed patents to extend its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant BLA.

For patents that might expire during the BLA review phase, the patent owner may request an interim patent term extension. If eligible, an interim patent term extension may be granted for a period of not more than one year. The patent owner may apply for not more than four subsequent interim extensions. Any interim extension granted will not be longer than the maximum period of extension allowed post-approval.

### Biosimilars and Exclusivity

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. To date, only a handful of biosimilars have been licensed under the BPCIA, and numerous biosimilars have been approved in Europe. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars.

Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical trial or trials. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. However, complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being worked out by the FDA.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing

the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

A biological product can also obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study.

The BPCIA is complex and continues to be interpreted and implemented by the FDA. In addition, recent government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate impact, implementation, and meaning of the BPCIA remains subject to significant uncertainty.

# Other Healthcare Laws and Compliance Requirements

Pharmaceutical companies are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business. Such laws include, without limitation: the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration, to induce, or in return for, either the referral of an individual, or the purchase or recommendation of an item or service for which payment may be made under any federal healthcare program; federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment to the federal government, including federal healthcare programs, that are false or fraudulent; the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal statutes which prohibit, among other things, executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters; HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their implementing regulations, which imposes certain requirements on certain types of individuals and entities relating to the privacy, security and transmission of individually identifiable health information; the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to annually report to the federal government, information related to payments or other transfers of value made to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and state and foreign law equivalents of each of the above federal laws, which, in some cases, differ from each other in significant ways, and may not have the same effect, thus complicating compliance efforts. If their operations are found to be in violation of any of such laws or any other governmental regulations that apply, they may be subject to penalties, including, without limitation, civil and criminal penalties, damages, fines, the curtailment or restructuring of operations, exclusion from participation in federal and state healthcare programs and individual imprisonment.

### Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any pharmaceutical or biological product for which we obtain regulatory approval. Sales of any product depend, in part, on the extent to which such product will be covered by third-party payors, such as federal, state, and foreign government healthcare programs, commercial insurance and managed healthcare organizations, and the level of reimbursement for such product by third-party payors. Decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the

higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization.

In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. Third party payors are increasingly challenging the prices charged for medical products and services, examining the medical necessity and reviewing the cost effectiveness of pharmaceutical or biological products, medical devices and medical services, in addition to questioning safety and efficacy. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit sales of any product. Decreases in third-party reimbursement for any product or a decision by a third-party payor not to cover a product could reduce physician usage and patient demand for the product.

# Healthcare Reform

The United States and some foreign jurisdictions are considering or have enacted a number of reform proposals to change the healthcare system. There is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by federal and state legislative initiatives, including those designed to limit the pricing, coverage, and reimbursement of pharmaceutical and biopharmaceutical products, especially under government-funded health care programs, and increased governmental control of drug pricing.

In March 2010, the ACA was signed into law, which substantially changed the way healthcare is financed by both governmental and private insurers in the United States, and significantly affected the pharmaceutical industry. The ACA contains a number of provisions of particular import to the pharmaceutical and biotechnology industries, including, but not limited to, those governing enrollment in federal healthcare programs, a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, and annual fees based on pharmaceutical companies' share of sales to federal health care programs. Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. Most recently, the Tax Cuts and Jobs Act of 2017 was enacted, which, among other things, removes penalties for not complying with ACA's individual mandate to carry health insurance. There is still uncertainty with respect to the impact President Trump's administration and the U.S. Congress may have, if any, and any changes will likely take time to unfold, and could have an impact on coverage and reimbursement for healthcare items and services covered by plans that were authorized by the ACA.

Other legislative changes have been proposed and adopted since the ACA was enacted, including aggregate reductions of Medicare payments to providers of 2% per fiscal year and reduced payments to several types of Medicare providers. Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. At the federal level, the Trump administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Additionally, on May 11, 2018, President Trump laid out his administration's "Blueprint" to reduce the cost of prescription drugs while preserving innovation and cures. The Department of Health and Human Services, or HHS, has already started the process of soliciting feedback on some of these measures and, at the same time,

is immediately implementing others under its existing authority. Although some of these, and other, proposals will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

# U.S. Foreign Corrupt Practices Act

The U.S. Foreign Corrupt Practices Act of 1977, or FCPA, prohibits U.S. corporations and individuals from engaging in certain activities to obtain or retain business or secure any improper advantage, or to influence a person working in an official capacity. It is illegal to pay, offer to pay or authorize the payment of anything of value to any employee or official of a foreign government or public international organization, or political party, political party official, or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity. The scope of the FCPA also includes employees and officials of state-owned or controlled enterprises, which may include healthcare professionals in many countries. Equivalent laws have been adopted in other foreign countries that impose similar obligations.

# Government Regulation Outside of the United States

In addition to regulations in the United States, we will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products. Because biologically sourced raw materials are subject to unique contamination risks, their use may be restricted in some countries.

Whether or not we obtain FDA approval of a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application, or CTA, much like the IND prior to the commencement of human clinical trials. In the European Union, for example, a CTA must be submitted to each country's national health authority and an independent ethics committee, much like the FDA and the IRB, respectively. Once the CTA is approved in accordance with a country's requirements, clinical trial development may proceed.

The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, the clinical trials are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

### Clinical Trials

Clinical trials of medicinal products in the European Union must be conducted in accordance with European Union and national regulations and the International Conference on Harmonization, or ICH, guidelines on GCPs. Additional GCP guidelines from the European Commission, focusing in particular on traceability, apply to clinical trials of advanced therapy medicinal products. If the sponsor of the clinical trial is not established within the European Union, it must appoint an entity within the European Union to act as its legal representative. The sponsor must take out a clinical trial insurance policy, and in most EU countries, the sponsor is liable to provide 'no fault' compensation to any study subject injured in the clinical trial.

Prior to commencing a clinical trial, the sponsor must obtain a clinical trial authorization from the competent authority, and a positive opinion from an independent ethics committee. The application for a clinical trial authorization must include, among other things, a copy of the trial protocol and an investigational medicinal

product dossier containing information about the manufacture and quality of the medicinal product under investigation. Currently, clinical trial authorization applications must be submitted to the competent authority in each EU Member State in which the trial will be conducted. Under the new Regulation on Clinical Trials, which is currently expected to take effect in 2019, there will be a centralized application procedure where one national authority takes the lead in reviewing the application and the other national authorities have only a limited involvement. Any substantial changes to the trial protocol or other information submitted with the clinical trial applications must be notified to or approved by the relevant competent authorities and ethics committees. Medicines used in clinical trials must be manufactured in accordance with cGMP. Other national and European Union-wide regulatory requirements also apply.

During the development of a medicinal product, the EMA and national medicines regulators within the European Union provide the opportunity for dialogue and guidance on the development program. At the EMA level, this is usually done in the form of scientific advice, which is given by the Scientific Advice Working Party of the Committee for Medicinal Products for Human Use, or CHMP. A fee is incurred with each scientific advice procedure. Advice from the EMA is typically provided based on questions concerning, for example, quality (chemistry, manufacturing and controls testing), nonclinical testing and clinical trials, and pharmacovigilance plans and risk-management programs. Advice is not legally binding with regard to any future marketing authorization application of the product concerned.

# Marketing Authorizations

To obtain regulatory approval of an investigational biological product under EU regulatory systems, we must submit a marketing authorization application. The application used to file the BLA in the United States is similar to that required in the European Union, with the exception of, among other things, country-specific document requirements. The process for doing this depends, among other things, on the nature of the medicinal product.

The centralized procedure results in a single marketing authorization, or MA, granted by the European Commission that is valid across the EEA (i.e., the European Union as well as Iceland, Liechtenstein and Norway). The centralized procedure is compulsory for human drugs that are: (i) derived from biotechnology processes, such as genetic engineering, (ii) contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative diseases, autoimmune and other immune dysfunctions and viral diseases, (iii) officially designated orphan medicines and (iv) advanced-therapy medicines, such as gene therapy, somatic cell therapy or tissue-engineered medicines. The centralized procedure may at the request of the applicant also be used in certain other cases. Therefore, the centralized procedure would be mandatory for the products we are developing.

The Committee for Advanced Therapies, or CAT, is responsible in conjunction with the CHMP for the evaluation of ATMPs. The CAT is primarily responsible for the scientific evaluation of ATMPs and prepares a draft opinion on the quality, safety and efficacy of each ATMP for which a marketing authorization application is submitted. The CAT's opinion is then taken into account by the CHMP when giving its final recommendation regarding the authorization of a product in view of the balance of benefits and risks identified. Although the CAT's draft opinion is submitted to the CHMP for final approval, the CHMP may depart from the draft opinion, if it provides detailed scientific justification. The CHMP and CAT are also responsible for providing guidelines on ATMPs and have published numerous guidelines, including specific guidelines on gene therapies and cell therapies. These guidelines provide additional guidance on the factors that the EMA will consider in relation to the development and evaluation of ATMPs and include, among other things, the preclinical studies required to characterize ATMPs; the manufacturing and control information that should be submitted in a marketing authorization application; and post-approval measures required to monitor patients and evaluate the long term efficacy and potential adverse reactions of ATMPs. Although these guidelines are not legally binding, we believe that our compliance with them is likely necessary to gain and maintain approval for any of our product candidates.

Under the centralized procedure in the European Union, the maximum timeframe for the evaluation of an MAA by the EMA is 210 days. This excludes so-called clock stops, during which additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP. At the end of the review period, the CHMP provides an opinion to the European Commission. If this is opinion favorable, the Commission may then adopt a decision to grant an MA. In exceptional cases, the CHMP might perform an accelerated review of an MAA in no more than 150 days (not including clock stops). This is usually when the product is of major interest from the point of view of public health and, in particular, from the viewpoint of therapeutic innovation.

The European Commission may grant a so-called "conditional marketing authorization" prior to obtaining the comprehensive clinical data required for an application for a full marketing authorization. Such conditional marketing authorizations may be granted for product candidates (including medicines designated as orphan medicinal products), if (i) the risk-benefit balance of the product candidate is positive, (ii) it is likely that the applicant will be in a position to provide the required comprehensive clinical trial data, (iii) the product fulfills an unmet medical need and (iv) the benefit to public health of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent in the fact that additional data are still required. A conditional marketing authorization may contain specific obligations to be fulfilled by the marketing authorization holder, including obligations with respect to the completion of ongoing or new studies, and with respect to the collection of pharmacovigilance data. Conditional marketing authorizations are valid for one year, and may be renewed annually, if the risk-benefit balance remains positive, and after an assessment of the need for additional or modified conditions and/or specific obligations. The timelines for the centralized procedure described above also apply with respect to the review by the CHMP of applications for a conditional marketing authorization.

The European Commission may also grant a so-called "marketing authorization under exceptional circumstances". Such authorization is intended for products for which the applicant can demonstrate that it is unable to provide comprehensive data on the efficacy and safety under normal conditions of use, because the indications for which the product in question is intended are encountered so rarely that the applicant cannot reasonably be expected to provide comprehensive evidence, or in the present state of scientific knowledge, comprehensive information cannot be provided, or it would be contrary to generally accepted principles of medical ethics to collect such information. Consequently, marketing authorization under exceptional circumstances may be granted subject to certain specific obligations, which may include the following:

- the applicant must complete an identified program of studies within a time period specified by the competent authority, the results of which form the basis of a reassessment of the benefit/risk profile;
- the medicinal product in question may be supplied on medical prescription only and may in certain cases be administered only under strict medical supervision, possibly in a hospital and in the case of a radio-pharmaceutical, by an authorized person; and

The package leaflet and any medical information must draw the attention of the medical practitioner to the fact that the particulars available concerning the medicinal product in question are as yet inadequate in certain specified respects.

A marketing authorization under exceptional circumstances is subject to annual review to reassess the risk-benefit balance in an annual reassessment procedure. Continuation of the authorization is linked to the annual reassessment and a negative assessment could potentially result in the marketing authorization being suspended or revoked. The renewal of a marketing authorization of a medicinal product under exceptional circumstances, however, follows the same rules as a "normal" marketing authorization. Thus, a marketing authorization under exceptional circumstances is granted for an initial five years, after which the authorization will become valid indefinitely, unless the EMA decides that safety grounds merit one additional five-year renewal. A marketing authorization under exceptional circumstances should not be granted when a conditional marketing authorization is more appropriate.

The European Union medicines rules expressly permit the EU Member States to adopt national legislation prohibiting or restricting the sale, supply or use of any medicinal product containing, consisting of or derived from a specific type of human or animal cell, such as embryonic stem cells. While the products we have in development do not make use of embryonic stem cells, it is possible that the national laws in certain EU Member States may prohibit or restrict us from commercializing our products, even if they have been granted an MA.

#### Data and Marketing Exclusivity

The European Union also provides opportunities for market exclusivity. Marketing authorization applications for generic medicinal products do not need to include the results of preclinical and clinical trials, but instead can refer to the data included in the marketing authorization of a reference product for which regulatory data exclusivity has expired. In the European Union, upon receiving marketing authorization, new chemical entities generally receive eight years of data exclusivity and an additional two years of market exclusivity. The two-year period may be extended to three years if during the first eight years a new therapeutic indication with significant clinical benefit over existing therapies is approved. If granted, data exclusivity prevents regulatory authorities in the European Union from referencing the innovator's data to assess a generic application. During the additional two-year period of market exclusivity, a generic marketing authorization can be submitted, and the innovator's data may be referenced, but no generic product can be marketed until the expiration of the market exclusivity. However, there is no guarantee that a product will be considered by the EU regulatory authorities to be a new chemical entity, and products may not qualify for data exclusivity.

There is a special regime for biosimilars, or biological medicinal products that are similar to a reference medicinal product but that do not meet the definition of a generic medicinal product, for example, because of differences in raw materials or manufacturing processes. For such products, the results of appropriate preclinical or clinical trials must be provided, and guidelines from the EMA detail the type of quantity of supplementary data to be provided for different types of biological product. There are no such guidelines for complex biological products, such as gene or cell therapy medicinal products, and so it is unlikely that biosimilars of those products will currently be approved in the European Union. However, guidance from the EMA states that they will be considered in the future in light of the scientific knowledge and regulatory experience gained at the time.

#### **Orphan Medicinal Products**

Products receiving orphan designation in the European Union can receive ten years of market exclusivity. During the ten year market exclusivity period, the EMA cannot accept another application for a marketing authorization, or grant a marketing authorization or accept an application to extend an existing marketing authorization, for the same therapeutic indication, in respect of a similar medicinal product. An orphan product can also obtain an additional two years of market exclusivity in the European Union for pediatric studies. No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications.

The criteria for designating an "orphan medicinal product" in the European Union are similar in principle to those in the United States. Under Article 3 of Regulation (EC) 141/2000, a medicinal product may be designated as orphan if (1) it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (2) either (a) such condition affects no more than five in 10,000 persons in the European Union when the application is made, or (b) the product, without the benefits derived from orphan status, would not generate sufficient return in the European Union to justify investment; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the European Union, or if such a method exists, the product will be of significant benefit to those affected by the condition, as defined in Regulation (EC) 847/2000. Orphan medicinal products are eligible for financial incentives such as reduction of fees or fee waivers. The application for orphan drug designation must be submitted before the MAA. The applicant will receive a fee reduction for the MAA if the orphan drug designation has been granted, but not if the designation is still pending at the time the marketing authorization is submitted. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The ten-year market exclusivity may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation, for example, if the product is sufficiently profitable not to justify maintenance of market exclusivity. Additionally, an MA may be granted to a similar product for the same indication at any time if:

- the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior;
- the applicant consents to a second orphan medicinal product application; or
- the applicant cannot supply enough orphan medicinal product.

#### Pediatric Investigation Plan

In the EMA, MAAs for new medicinal products not authorized have to include the results of trials conducted in the pediatric population, in compliance with a pediatric investigation plan, or PIP, agreed with the EMA's Pediatric Committee, or PDCO. The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the drug for which an MA is being sought. The PDCO can grant a deferral of the obligation to implement some or all of the measures of the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Further, the obligation to provide pediatric clinical trial data can be waived by the PDCO when these data are not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Once the MA is obtained in all EU Member States and trial results are included in the product information, even when negative, the product is eligible for a six-months supplementary protection certificate extension.

#### Post-Approval Controls

The holder of an MA must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports, or PSURs.

All new MAAs must include a risk management plan, or RMP, describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the marketing authorization. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies. RMPs and PSURs are routinely available to third parties requesting access, subject to limited redactions.

All advertising and promotional activities for the product must be consistent with the approved summary of product characteristics, and therefore all off-label promotion is prohibited. Direct-to-consumer advertising of prescription medicines is also prohibited in the European Union. Although general requirements for advertising and promotion of medicinal products are established under EU directives, the details are governed by regulations in each EU Member State and can differ from one country to another.

# Pricing and Reimbursement

Governments influence the price of medicinal products in the European Union through their pricing and reimbursement rules and control of national healthcare systems that fund a large part of the cost of those products

to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular product candidate to currently available therapies. Other EU Member States allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on healthcare costs in general, particularly prescription medicines, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

#### PRIME Scheme

In July 2016 the EMA launched PRIME scheme. PRIME is a voluntary scheme aimed at enhancing the EMA's support for the development of medicines that target unmet medical needs. It is based on increased interaction and early dialogue with companies developing promising medicines, to optimize their product development plans and speed up their evaluation to help them reach patients earlier. Product developers that benefit from PRIME designation can expect to be eligible for accelerated assessment but this is however not guaranteed. The benefits of a PRIME designation includes the appointment of a rapporteur from the CHMP before submission of an MAA, early dialogue and scientific advice at key development milestones, and the potential to qualify products for accelerated review earlier in the application process.

#### **UK Specials Regulation**

The UK's Human Medicines Regulations 2012 allow for the manufacture and supply of medicinal products not authorized for marketing to patients with special needs at the request of the healthcare professional responsible for the patient's care (these products are referred to as "specials"). A special may only be supplied in: (i) response to an unsolicited order from a healthcare professional responsible for the care of the patient, (ii) the product is manufactured and assembled in accordance with the specifications of that healthcare professional to fulfil the special needs of the individual patient which cannot be met by products already authorized for marketing, and (iii) the product is manufactured under a specials license granted by the UK's MHRA.

Manufacturing a special also imposes a five year record retention requirements subject to review by the MHRA, including details of any suspected adverse reaction to the product so sold or supplied of which the person is aware or subsequently becomes aware, as well as a continuing obligation to notify the MHRA of any suspected adverse reaction to the medicinal product which is a serious adverse reaction.

### **Employees**

As of March 31, 2018, we had 59 employees, including 11 employees with M.D. or Ph.D. degrees. Of these full-time employees, 45 are engaged in research and development activities. None of our employees is subject to a collective bargaining agreement or represented by a trade or labor union. We consider our relationship with our employees to be good.

#### **Facilities**

Our principal office is located at 430 East 29th Street, 10th Floor, New York, NY 10016, USA, where we lease 5,887 square feet of office space. We lease this office space under a lease that terminates on December 31, 2021.

We also lease the ground rights where our 29,000 square foot manufacturing facility is located, at 92 Britannia Walk, London N1 7NQ, United Kingdom. This lease terminates February 2, 2021 and we have the option to extend until February 2, 2026.

# **Legal Proceedings**

We are not subject to any material legal proceedings.

#### MANAGEMENT

#### **Executive Officers and Directors**

The following table sets forth certain information of each executive officer and non-employee director of MeiraGTx Limited, including their ages as of May 29, 2018.

<u>Name</u>	Age	Position
Executive Officers		
Alexandria Forbes, Ph.D.	53	President and Chief Executive Officer and Director
Richard Giroux	45	Chief Operating Officer
Stuart Naylor, Ph.D.	54	Chief Development Officer and Director
Non-employee Directors		
Keith R. Harris, Ph.D. (1)(2)(3)	65	Chairman of the Board
Ellen Hukkelhoven, Ph.D.	31	Director
Arnold J. Levine, Ph.D. (2)	78	Director
Joel S. Marcus (1)(3)	70	Director
Neil Mendoza (1)(2)(3)	58	Director
Gregory S. Moss	34	Director
Thomas E. Shenk, Ph.D.	71	Director

- Member of the audit committee.
- Member of the compensation committee.

  Member of the nominating and corporate governance committee.

#### **Executive Officers**

Alexandria Forbes, Ph.D. has served as our President, Chief Executive Officer and member of our board of directors since March 2015. Prior to joining MeiraGTx, Dr. Forbes served as Senior Vice President of Commercial Operations at Kadmon Holdings, Inc., a biopharmaceutical company, from September 2013 to April 2015, and currently serves as a member of its board of directors. Effective upon the effectiveness of the registration statement of which this prospectus forms a part, Dr. Forbes will resign from the board of directors of Kadmon Holdings, Inc. A subsidiary of Kadmon Holdings, Inc. is a holder of more than 5% of our outstanding shares. Prior to Kadmon Holdings, Inc., Dr. Forbes spent eleven years as a healthcare investor at Sivik Global Healthcare (formerly Argus Partners), a healthcare hedge fund, from August 2001 to November 2008, and at Meadowvale Asset Management, a healthcare hedge fund, from January 2010 to June 2012. Before entering the hedge fund industry, Dr. Forbes was a Human Frontiers/Howard Hughes postdoctoral fellow at the Skirball Institute of Biomolecular Medicine at NYU Langone Medical Center from March 1997 to September 2000. Prior to this, Dr. Forbes was a research fellow at Duke University, and also at the Carnegie Institute at Johns Hopkins University. Dr. Forbes received an M.A. in Natural Sciences from Cambridge University and a Ph.D. in Molecular Genetics from Oxford University. Our board of directors believes Dr. Forbes' extensive academic and clinical experience, as well as her knowledge of the industry, qualifies her to serve on our board of directors.

Richard Giroux has served as our Chief Operating Officer since March 2015. Mr. Giroux joined MeiraGTx from Sarissa Capital Management LP, an activist healthcare hedge fund, where he was a partner from March 2014 to March 2015. Prior to Sarissa Capital Management LP, Mr. Giroux was a founding partner and healthcare portfolio manager of Meadowvale Partners, a multi-strategy hedge fund, from January 2010 until June 2012. Prior to Meadowvale Partners, he was a partner at Sivik Global Healthcare (formerly Argus Partners), a healthcare hedge fund, from August 2001 to November 2008. Prior to that, he worked at investment banks Salomon Smith Barney and Goldman Sachs. Mr. Giroux received a B.A. in Economics from Yale University.

Stuart Naylor, Ph.D. has served as our Chief Development Officer and a member of our board of directors since April 2015. From April 2015 to April 2016, Dr. Naylor was Chief Executive Officer of Athena

Vision Limited, a biotechnology company. From June 2013 to April 2015, Dr. Naylor served as managing director of Coltivare Ltd., a healthcare consulting company. From 2008 to 2013, Dr. Naylor was Executive Director and Chief Scientific Officer of Oxford BioMedica plc, a gene therapy company. Prior to joining Oxford BioMedica plc, Dr. Naylor focused on translational cancer research at the Institute of Cancer Research in London. Dr. Naylor has a B.S.C. in microbiology and virology from the University of Warwick, an M.S. in Immunology from Kings College London, and a Ph.D. from the Imperial Cancer Research Fund laboratory studying ovarian cancer and cytokine biology. Our board of directors believes Dr. Naylor's extensive academic and clinical experience, as well as his knowledge of the industry, qualifies him to serve on our board of directors.

### **Non-employee Directors**

*Keith Harris*, *Ph.D.* has served as a member of our board of directors since June 2015 and served as chairman of our board of directors since February 2018. Dr. Harris is a London-based investment banker and financier with a 25-year career as a senior corporate finance and takeover advisor. Since 1999, Dr. Harris has been the chairman of Keith Harris & Associates, a sports consulting firm. Dr. Harris previously served as Chief Executive Officer of HSBC Investment Bank from 1994 to 1999 and Seymour Pierce Holdings Limited, a subsidiary of which, Seymour Pierce Limited, was acquired in a pre-paid administration under U.K. law in 2013. Dr. Harris received a B.A. in business and economics from the University of Bradford and a Ph.D. in Economics from the University of Surrey. Our board of directors believes that Dr. Harris' financial knowledge and experience qualifies him to serve as a member of our board of directors.

Ellen Hukkelhoven, Ph.D. has served as a member of our board of directors since October 2017. Dr. Hukkelhoven currently serves as a Senior Analyst at Perceptive Advisors, a leading healthcare investment firm. Prior to joining Perceptive Advisors in 2013, Dr. Hukkelhoven received an A.B. in molecular biology from Princeton University and a Ph.D. in cancer biology from Memorial Sloan Kettering Cancer Center. Our board of directors believes that Dr. Hukkelhoven's academic and biotechnology investing experience qualifies her to serve as a member of our board of directors.

Arnold J. Levine, Ph.D. has served as a member of our board of directors since February 2016. Dr. Levine currently serves as a professor emeritus at the Institute for Advanced Study at Princeton University. Dr. Levine was a director of Imclone Systems Incorporated from 2000 to 2003. He was a professor in the Department of Molecular Biology at Princeton University from 1984 until 1996, where he was named the Harry C. Wiess Professor in Life Sciences and was the chairman of the department. Dr. Levine received a B.A. from Harpur College, State University of New York at Binghamton and a Ph.D. in microbiology from the University of Pennsylvania. Our board of directors believes Dr. Levine's expertise and experience serving as a director in the pharmaceutical sector and his academic background provides him with the qualifications and skills to serve on our board of directors.

Joel S. Marcus has served as a member of our board of directors since June 2015. Mr. Marcus founded Alexandria Real Estate Equities, Inc., a real estate investment trust, and currently serves as Executive Chairman after previously serving as its Chairman since May 2007, Chief Executive Officer since March 1997 and a director since its founding in 1994. Mr. Marcus also co-founded and leads Alexandria Venture Investments, LLC which is a strategic venture arm of Alexandria Real Estate Equities, Inc. and the managing member of a holder of more than 5% of our outstanding shares. Prior to founding Alexandria Real Estate Equities, Inc., Mr. Marcus specialized in corporate finance and capital markets, venture capital and mergers and acquisitions with special expertise in the biopharmaceutical industry. Mr. Marcus received a B.A. and a J.D. from the University of California, Los Angeles. Our board of directors believes that Mr. Marcus' extensive experience in the life science real estate industry and as a chief executive officer, as well as his training as a C.P.A. and attorney, provide him with the qualifications and skills to serve on our board of directors.

*Neil Mendoza* has served as a member of our board of directors since June 2015. In 1986, Mr. Mendoza founded the custom marketing and publishing agency Forward, subsequently renamed Bookmark Content and

Communications, a subsidiary of WPP plc. Mr. Mendoza is the Chairman of Victoria Private Investment Office, a London-based investment advisory firm, which he joined in 2010. He received a M.A. in Geography from Oxford University. Our board of directors believes Mr. Mendoza's extensive experience with investments provides him with the qualifications and skills to serve on our board of directors.

Gregory S. Moss has served as a member of our board of directors since May 2018. Mr. Moss joined Kadmon Holdings, Inc. in 2012 and has served as its Senior Vice President and Deputy General Counsel since 2012. He was also Acting General Counsel and Compliance Officer of MeiraGTx Limited from April 2015 to December 2016. He received a combined Bachelor of Arts and Bachelor of Laws degree from Macquarie University in 2007. Our board of directors believes Mr. Moss' experience serving as general counsel of a biopharmaceutical company provides him with qualifications and skills to serve on our board of directors.

Thomas E. Shenk, Ph.D. has served as a member of our board of directors since June 2015. Dr. Shenk has been the James A. Elkins Jr. Professor of Life Sciences in the Department of Molecular Biology at Princeton University since 1984. He received a B.S. from University of Detroit and a Ph.D. from Rutgers University. Dr. Shenk served on the board of directors of Merck and Co. Inc., a pharmaceutical company from 2001 to 2012. Dr. Shenk currently serves as a director of Vical Incorporated, a biopharmaceutical company, and Kadmon Holdings, Inc., a biopharmaceutical company. Effective upon the effectiveness of this registration statement, Dr. Shenk will resign from the board of directors of Kadmon Holdings, Inc. Our board of directors believes Dr. Shenk's expertise and experience serving as a director in the pharmaceutical sector and his academic background provides him with the qualifications and skills to serve on our board of directors.

### **Family Relationships**

There are no family relationships among any of our directors or executive officers.

#### **Board Composition and Election of Directors**

### Director Independence

Our board of directors currently consists of nine members. Our board of directors has determined that, of our nine directors, Keith Harris, Ellen Hukkelhoven, Arnold Levine, Joel Marcus, Neil Mendoza and Gregory Moss do not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is "independent" as that term is defined under the rules of The Nasdaq Stock Market LLC, or Nasdaq. The listing requirements of Nasdaq, "independent directors" must comprise a majority of our board of directors within one year of closing of this offering.

### **Classified Board of Directors**

In accordance with our new articles of association that will go into effect upon the closing of this offering, our board of directors will be divided into three classes with staggered, three-year terms. At each annual meeting of shareholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election. The election of directors will be by plurality of votes cast by the shareholders entitled to vote. Effective upon the closing of this offering, our directors will be divided among the three classes as follows:

- the Class I directors will be Arnold Levine, Gregory Moss and Thomas Shenk, and their terms will expire at our first annual meeting of shareholders following this offering;
- the Class II directors will be Ellen Hukkelhoven, Joel Marcus and Stuart Naylor, and their terms will expire at our second annual meeting of shareholders following this offering; and
- the Class III directors will be Alexandria Forbes, Keith Harris and Neil Mendoza, and their terms will expire at the third annual meeting
  of shareholders following this offering.

Our new articles of association that will go into effect upon the closing of this offering will provide that the authorized number of directors may be changed only by resolution of the board of directors. Any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors. The division of our board of directors into three classes with staggered three-year terms may delay or prevent a change of our management or a change in control of our company.

## **Board Leadership Structure**

Our board of directors is currently chaired by Keith Harris. Our corporate governance guidelines provide that, if the chairman of the board is a member of management or does not otherwise qualify as independent, the independent directors of the board may elect a lead director. The lead director's responsibilities would include, but would not be limited to: presiding over all meetings of the board of directors at which the chairman is not present, including any executive sessions of the independent directors; approving board meeting schedules and agendas; and acting as the liaison between the independent directors and the chief executive officer and chairman of the board. Our corporate governance guidelines further provide the flexibility for our board of directors to modify our leadership structure in the future as it deems appropriate.

# Role of the Board in Risk Oversight

One of the key functions of our board of directors is informed oversight of our risk management process. Our board of directors does not have a standing risk management committee, but rather administers this oversight function directly through our board of directors as a whole, as well as through various standing committees of our board of directors that address risks inherent in their respective areas of oversight. In particular, our board of directors is responsible for monitoring and assessing strategic risk exposure and our audit committee has the responsibility to consider and discuss our major financial risk exposures and the steps our management has taken to monitor and control these exposures, including guidelines and policies to govern the process by which risk assessment and management is undertaken. Our audit committee also monitors compliance with legal and regulatory requirements. Our nominating and corporate governance committee monitors the effectiveness of our corporate governance practices, including whether they are successful in preventing illegal or improper liability-creating conduct. Our compensation committee assesses and monitors whether any of our compensation policies and programs has the potential to encourage excessive risk-taking. While each committee is responsible for evaluating certain risks and overseeing the management of such risks, our entire board of directors is regularly informed through committee reports about such risks.

#### **Board Committees**

Our board of directors has established three standing committees—audit, compensation and nominating and corporate governance—each of which operates under a charter that has been approved by our board of directors. Upon our listing on the Nasdaq Global Select Market, each committee's charter will be available under the "Corporate Governance" section of our website at <a href="https://www.meirgtx.com">www.meirgtx.com</a>. The reference to our website address does not constitute incorporation by reference of the information contained at or available through our website, and you should not consider it to be a part of this prospectus.

# **Audit Committee**

The audit committee's responsibilities include:

- appointing, approving the compensation of, and assessing the independence of our registered public accounting firm;
- · overseeing the work of our registered public accounting firm, including through the receipt and consideration of reports from such firm;

- reviewing and discussing with management and the registered public accounting firm our annual and quarterly financial statements and related disclosures;
- coordinating our board of directors' oversight of our internal control over financial reporting, disclosure controls and procedures and code of business conduct and ethics;
- discussing our risk management policies;
- · meeting independently with our internal auditing staff, if any, registered public accounting firm and management;
- · reviewing and approving or ratifying any related person transactions; and
- preparing the audit committee report required by Securities Exchange Commission, or SEC, rules.

The members of our audit committee are Keith Harris, Joel Marcus and Neil Mendoza. Keith Harris serves as the chairperson of the committee. All members of our audit committee meet the requirements for financial literacy under the applicable listing rules of Nasdaq, or Nasdaq rules. Our board of directors has determined that Keith Harris, Joel Marcus and Neil Mendoza meet the independence requirements of Rule 10A-3 under the Exchange Act and the applicable Nasdaq rules. Our board of directors has determined that each of Keith Harris and Joel Marcus is an "audit committee financial expert" as defined by applicable SEC rules and has the requisite financial sophistication as defined under the applicable Nasdaq rules.

#### **Compensation Committee**

The compensation committee's responsibilities include:

- reviewing and approving, or recommending for approval by the board of directors, the compensation of our CEO and our other executive officers;
- · overseeing and administering our cash and equity incentive plans;
- · reviewing and making recommendations to our board of directors with respect to director compensation;
- · reviewing and discussing annually with management our "Compensation Discussion and Analysis," to the extent required; and
- preparing the annual compensation committee report required by SEC rules, to the extent required.

The members of our compensation committee are Keith Harris, Arnold Levine and Neil Mendoza. Keith Harris serves as the chairperson of the committee. Our board of directors has determined that each of Keith Harris, Arnold Levine and Neil Mendoza is independent under the applicable Nasdaq rules, including the Nasdaq rules specific to membership on the compensation committee, and is a "non-employee director" as defined in Rule 16b-3 promulgated under the Exchange Act.

### Nominating and Corporate Governance Committee

The nominating and corporate governance committee's responsibilities include:

· identifying individuals qualified to become board members;

- · recommending to our board of directors the persons to be nominated for election as directors and to each board committee;
- developing and recommending to our board of directors corporate governance guidelines, and reviewing and recommending to our board of directors proposed changes to our corporate governance guidelines from time to time; and
- · overseeing a periodic evaluation of our board of directors.

The members of our nominating and corporate governance committee are Keith Harris, Joel Marcus and Neil Mendoza. Joel Marcus serves as the chairperson of the committee. Our board of directors has determined that Keith Harris, Joel Marcus and Neil Mendoza are independent under the applicable Nasdaq rules.

### Compensation Committee Interlocks and Insider Participation

No member of our compensation committee is or has been our current or former officer or employee. None of our executive officers served as a director or a member of a compensation committee (or other committee serving an equivalent function) of any other entity, one of whose executive officers served as a director or member of our compensation committee during the fiscal year ended December 31, 2017.

#### **Code of Ethics and Code of Conduct**

We have adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. Upon our listing on the Nasdaq Global Select Market, our code of business conduct and ethics will be available under the "Corporate Governance" section of our website at www.meiragtx.com. In addition, we intend to post on our website all disclosures that are required by law or the Nasdaq rules concerning any amendments to, or waivers from, any provision of the code. The reference to our website address does not constitute incorporation by reference of the information contained at or available through our website, and you should not consider it to be a part of this prospectus.

#### EXECUTIVE AND DIRECTOR COMPENSATION

#### **Executive Compensation**

This section discusses the material components of the executive compensation program for our executive officers who are named in the "2017 Summary Compensation Table" below. In 2017, our "named executive officers" and their positions were as follows:

- Alexandria Forbes, Ph.D., President and Chief Executive Officer;
- Richard Giroux, Chief Operating Officer; and
- Stuart Naylor, Ph.D., Chief Development Officer.

This discussion may contain forward-looking statements that are based on our current plans, considerations, expectations and determinations regarding future compensation programs. Actual compensation programs that we adopt following the completion of this offering may differ materially from the currently planned programs summarized in this discussion.

### 2017 Summary Compensation Table

The following table sets forth information concerning the compensation of our named executive officers for the year ended December 31, 2017.

			Bonus	Option Awards	All Other Compensation	
Name and Principal Position	Year	Salary (\$)	(\$)(1)	(\$)(2)	(\$)(3)	Total (\$)
Alexandria Forbes, Ph.D.	2017	450,000	490,000	165,969	16,200	1,122,169
President and Chief Executive Officer						
Richard Giroux	2017	400,000	440,000	153,202	_	993,202
Chief Operating Officer						
Stuart Naylor, Ph.D. (4)	2017	257,800	528,900	25,534	25,780	838,014
Chief Development Officer						

For Dr. Forbes and Mr. Giroux, amounts reflect a bonus accrued in 2017 and paid in early 2018 in connection with our achieving a fundraising milestone. For Dr. Naylor, amount reflects a \$400,000 discretionary bonus paid in the first quarter of 2018 attributable to performance in 2017 and \$128,900 accrued in 2017 and paid in early 2018 in connection with our achieving a fundraising milestone.

# Narrative to Summary Compensation Table

Base Salaries

The named executive officers receive a base salary to compensate them for services rendered to our company. The base salary payable to each named executive officer is intended to provide a fixed component of compensation reflecting the executive's skill set, experience, role and responsibilities.

Pursuant to the terms of their employment agreements, the base salaries of Dr. Forbes and Mr. Giroux were initially set at \$390,000 and \$320,000, respectively, and were increased to \$450,000 and \$400,000,

Amounts reflect the full grant-date fair value of options granted during 2017 computed in accordance with ASC Topic 718, rather than the amounts paid to or realized by the named individual. We provide information regarding the assumptions used to calculate the value of all option awards made to executive officers in Note 10 to our consolidated financial statements included elsewhere in this prospectus.

Amounts shown represent employer contributions to our 401(k) plan for Dr. Forbes and a defined contribution pension scheme in the UK for Dr. Naylor.

Amounts shown for Dr. Naylor were paid in pounds sterling and converted to U.S. dollars based on an average exchange rate for 2017 of \$1.289 to £1.00.

respectively, in April 2016, in connection with our attaining a fundraising milestone. In addition, the base salaries of Dr. Forbes and Mr. Giroux were subsequently increased to \$580,000 and \$495,000, respectively, in connection with our attaining a second fundraising milestone in March 2018.

Dr. Naylor received an initial annual base salary of £200,000 pursuant to the terms of his employment agreement. His annual base salary was increased to £275,000 in January 2018.

#### **Bonuses**

Dr. Forbes and Mr. Giroux are entitled to guaranteed annual cash bonus payments and may receive performance-based bonuses pursuant to the terms of their employment agreements, as described in more detail below under "Executive Compensation Arrangements—Dr. Forbes and Mr. Giroux." In January 2018, the compensation committee determined that the guaranteed and performance based bonus amounts payable to Dr. Forbes and Mr. Giroux for 2017 would be \$1,078,000 and \$968,000, respectively, and that these amounts would be paid only upon the company's satisfaction of performance milestones relating to (i) receipt of grant funds exceeding a threshold amount, (ii) equity investments or other upfront payments resulting in a cash balance above a threshold amount or (iii) the closing of an initial public offering. Consequently, Dr. Forbes and Mr. Giroux will become entitled to these bonus payments no later than the closing of this offering. In addition, in January 2018, Dr. Forbes and Mr. Giroux were paid bonuses that accrued in 2017 in connection with our achieving a fundraising milestone. These bonuses are included in the "bonus" column of the 2017 Summary Compensation Table above.

Pursuant to his employment agreement, Dr. Naylor has the opportunity to earn an annual discretionary bonus. In January 2018 the compensation committee determined to pay Dr. Naylor a bonus for 2017 performance of \$400,000.

#### **Equity Compensation**

Our named executive officers currently hold restricted ordinary shares and options to purchase ordinary shares. In September 2017, the named executive officers were granted options as set forth below. The options generally vest as to 25% of the shares subject to the option on the first anniversary of the grant date and in 36 substantially equal monthly installments thereafter.

Pursuant to their employment agreements, Dr. Forbes and Mr. Giroux are entitled to annual grants of restricted ordinary shares in amounts as determined by the compensation committee with respect to Dr. Forbes or by our chief executive officer with respect to Mr. Giroux. For 2017, the compensation committee, with respect to Dr. Forbes, and the chief executive officer, with respect to Mr. Giroux, determined not to make any such grants.

The following table sets forth the options granted to our named executive officers in the 2017 fiscal year.

Named Executive Officer	2017 Options Granted
Alexandria Forbes, Ph.D.	83,741
Richard Giroux	77,299
Stuart Naylor, Ph.D	12,883

In January 2018, the named executive officers were granted options to purchase our ordinary shares in the following amounts: Dr. Forbes 103,066, Mr. Giroux 96,624 and Dr. Naylor 90,182. The options vest in accordance with our standard vesting schedule described above.

Dr. Forbes and Mr. Giroux are also entitled to certain equity-based incentive awards upon our achievement of certain corporate or financial milestones as set forth in their employment agreements. In

connection with our attaining a fundraising milestone on March 1, 2018, each of Dr. Forbes and Mr. Giroux became entitled to a grant of fully vested shares in an amount equal to 1.5% of our outstanding shares on a fully diluted basis plus payment of any associated income taxes incurred by the named executive officer. In March 2018, we issued each of Dr. Forbes and Mr. Giroux 275,081 vested ordinary shares and paid \$1,680,101 for the associated taxes incurred by each of Dr. Forbes and Mr. Giroux.

On the first to occur of the effectiveness of the registration statement of which this prospectus forms a part and a change in control, each of Dr. Forbes and Mr. Giroux is also entitled to a grant of restricted shares in an amount equal to 2.5% of our outstanding shares on a fully diluted basis, which we refer to as the Executive IPO Grants. One-third of the restricted shares subject to the Executive IPO Grants will be vested at grant and the remaining shares will vest in eight quarterly installment beginning three months after effectiveness of this registration statement. We currently expect to issue to Dr. Forbes and Mr. Giroux an aggregate of 435,450 vested restricted shares and 870,898 restricted shares in respect of the Executive IPO Grants on the date the registration statement of which this prospectus forms a part becomes effective or, if later, on the date we file a registration statement on Form S-8 covering the issuance of the shares. Pursuant to the terms of their employment agreements, the company will satisfy any taxes incurred by Dr. Forbes or Mr. Giroux in connection with the Executive IPO Grants. Based on an assumed initial public offering price of \$15.00 per ordinary share, which is the midpoint of the price range set forth on the cover page of this prospectus, we expect our tax obligation with respect to the 435,450 vested restricted shares will be \$6.5 million.

In connection with this offering adopt a 2018 Incentive Award Plan, referred to below as the 2018 Plan, in order to facilitate the grant of cash and equity incentives to directors, employees (including our named executive officers) and consultants of our company and certain of its affiliates and to enable our company and certain of its affiliates to obtain and retain services of these individuals, which is essential to our long-term success. Following the effectiveness of the 2018 Plan, we will not make any further grants under the MeiraGTx Limited 2016 Equity Incentive Plan, referred to below as the 2016 Plan, under which we have previously made grants of equity and equity-based awards to our named executive officers and other key employees. For additional information about the 2018 Plan and the 2016 Plan, please see the section titled "Incentive Plans" below.

Other Elements of Compensation

#### Retirement Plans

We maintain a 401(k) retirement savings plan for our employees employed in the United States who satisfy certain eligibility requirements and contribute to defined contribution pension schemes on behalf of our employees employed in the United Kingdom. Our named executive officers are eligible to participate in our 401(k) plan in the United States and receive pension contributions in the United Kingdom on the same terms as other full-time employees in the applicable jurisdiction. We match 100% of employee contributions to our 401(k) plan, up to 6% of eligible compensation. We believe that providing a vehicle for tax-deferred retirement savings adds to the overall desirability of our executive compensation package and further incentivizes our employees, including our named executive officers, in accordance with our compensation policies.

#### **Employee Benefits**

All of our full-time employees, including our named executive officers, are eligible to participate in our health and welfare plans, subject to the same terms and eligibility requirements.

### **Outstanding Equity Awards at Fiscal Year-End**

The following table summarizes the number of ordinary shares underlying outstanding equity incentive plan awards for each named executive officer as of December 31, 2017.

		Option Awards				Stock Awards	
Name	Grant Date	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable (1)	Option Exercise Price (\$)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)(2)	Market Value of Shares or Units of Stock That Have Not Vested (\$)
Alexandria Forbes, Ph.D.	3/4/2016	26,491	34,060	7.73	3/4/2026		
	9/20/2017	_	83,741	2.64	9/20/2027	_	_
Richard Giroux	3/4/2016	21,418	27,538	7.73	3/4/2026	_	_
	9/20/2017	_	77,299	2.64	9/20/2027	_	_
Stuart Naylor, Ph.D.	4/24/2015	_	_	_	_	25,669	37,220
	3/4/2016	11,272	14,494	7.73	3/4/2026	_	_
	9/20/2017	_	12,883	2.64	9/20/2027	_	_

The options vest as to 25% of the total shares underlying the option on the first anniversary of the grant date and in equal monthly installments over the ensuing 36 months, subject to the holder's continued employment with us through the applicable vesting date and, for Dr. Forbes and Mr. Giroux, accelerated vesting upon a qualifying termination of employment as described in more detail below under "Executive Compensation Arrangements—Dr. Forbes and Mr. Giroux."

The restricted shares vest ratably on a daily basis over three years ending April 24, 2018.

### **Executive Compensation Arrangements**

We have entered into employment agreements with each of our named executive officers. Certain key terms of these agreements are described below.

#### Dr. Forbes and Mr. Giroux

We entered into employment agreements with Dr. Forbes and Mr. Giroux in February 2016. The agreements have an initial term of three years and automatically renew for successive one year periods unless notice of non-renewal is provided by either party at least 90 days prior to the expiration of the then-current term.

Pursuant to the employment agreements, Dr. Forbes and Mr. Giroux are entitled to annual base salaries in the amounts described above under "Base Salaries," annual cash bonuses equal to 100% of their respective base salaries, referred to as the guaranteed bonus, and the opportunity to earn annual performance-based bonuses targeted at 60% of base salary for Dr. Forbes and 50% of base salary for Mr. Giroux, referred to as the performance bonus.

In the event we complete a strategic collaboration resulting in upfront payments to us, each of Dr. Forbes and Mr. Giroux is entitled to a cash bonus in an amount determined by the compensation committee and, with respect to Mr. Giroux, the chief executive officer, provided that such bonus will not be less than 1% of the upfront payments received by us in such collaboration. There is no limit on the number of bonuses the executives may receive per year pursuant to this arrangement.

In the event either of Dr. Forbes's or Mr. Giroux's employment is terminated due to death or disability, or Dr. Forbes or Mr. Giroux resigns employment without good reason, which includes the executive's election not to renew the term of the employment agreement, the executive (or the executive's estate or beneficiary) is entitled to receive the executive's base salary, guaranteed bonus, and performance bonus as if the executive's employment had continued for an additional 12-month period.

In the event either of Dr. Forbes or Mr. Giroux is terminated by us for any reason other than cause, including due to a change in control, the company elects not to renew the term of the employment agreement, or

Dr. Forbes or Mr. Giroux resigns for good reason, the executive is entitled to (i) three months' notice of termination or pay in lieu of notice, (ii) receive the executive's base salary, guaranteed bonus, and performance bonus as if the executive's employment had continued for an additional 24 month period (including a pro-rated guaranteed bonus and performance bonus for any stub periods), (iii) employee benefits and post-employment employee benefits and conversion rights in accordance with the terms and conditions of the plans, policies, programs, or perquisites in which the executive participates for a period of 24 months following the end of the then-current term, (iv) incentive and deferred compensation incentive rights in accordance with the terms and conditions of the incentive and deferred compensation plans in which the executive participates; provided, however, that the executive shall be deemed fully vested in any incentive and deferred compensation awards under such plans upon a termination, (v) accelerated vesting of any unvested restricted shares and equity incentive awards, (vi) to the extent not yet granted, be granted fully vested ordinary shares for the restricted shares provided for under the Executive IPO Grants or other awards to which the executive may at the time be entitled as if all conditions applicable to such award were met, and (vii) be paid, within 30 days of termination, a cash termination fee equivalent to 1.50% for Dr. Forbes, or 1% for Mr. Giroux, of the average "market value" of our shares during the 90-trading day period prior to the termination plus payment of any taxes owed by the executive as a result of such termination fee. For purposes of the employment agreements, "market value" means the number obtained by multiplying (x) the aggregate number of shares of our voting and non-voting common equity (including shares held by employees and affiliates) by (y) the average of the last closing prices of our common equity in the principal market for such common equity, as adjuste

For purposes of the employment agreements, "cause" means the executive's (i) conviction of a felony involving moral turpitude, (ii) embezzlement, or (iii) intentional and willful misconduct that may subject us to criminal liability, which misconduct is not cured within 30 days after written notice to the executive of such conduct, if curable.

For purposes of the employment agreements, "good reason" means (i) any material diminution of the executive's title, duties, work responsibilities, authority, or status, or the assignment of duties that would typically be performed by someone in the executive's position to an individual other than the executive, (ii) a material negative change in the executive's reporting structure, (iii) a change in control, (iv) a reduction in the executive's then current base salary, (v) a change in the executive's principal place of employment to a location more than 15 miles from Manhattan, New York, (vi) our breach of the employment agreement that is not cured within 30 days after receiving notice of such breach, (vii) our insistence that the executive perform or condone any illegal conduct, or (viii) a hostile or abusive work environment or harassment.

### Dr. Naylor

We have entered into an employment agreement with Dr. Naylor, pursuant to which he serves as our Chief Development Officer. The agreement is for an unspecified term and may be terminated by either party upon no less than 12-months' notice, or pay in lieu of notice.

Pursuant to his employment agreement, Dr. Naylor received an initial annual base salary of £200,000, which was increased to £275,000 in January 2018, and has the opportunity to earn discretionary annual bonuses.

Dr. Naylor's employment agreement contains certain restrictive covenants pursuant to which he has agreed to refrain from competing with us or soliciting certain of our clients, customers or employees, in each case, for a period of 12 months following his termination of employment.

# **Director Compensation**

We provide our non-employee directors with meeting fees for each meeting of the board or committee attended, in person or telephonically. Non-employee directors receive \$4,000 (or \$6,000 for the chairman) for

each meeting of the board attended in person and \$1,000 for each meeting of the board attended telephonically. Non-employee directors who are on committees of the board receive \$500 (or \$1,000 for the chairman of the committee) for each committee meeting attended in person or telephonically. Directors who are also employees of our company do not receive compensation for their service on our board.

In 2016, we granted certain non-employee directors options to purchase our ordinary shares. The options vested as to 50% of the shares upon grant and as to 50% of the shares on the first anniversary of the grant date. No options were granted to non-employee directors during 2017.

The following table sets forth information regarding the compensation of our non-employee directors earned during 2017:

	Fees Earned or	
	Paid in Cash	
Name	(\$)	Total (\$)
Thomas E. Shenk, Ph.D.	29,000	29,000
Keith R. Harris, Ph.D.	26,000	26,000
Ellen Hukkelhoven, Ph.D.	_	_
Arnold J. Levine, Ph.D.	23,000	23,000
Joel S. Marcus, J.D.	24,500	24,500
Neil Mendoza	21,500	21,500

The table below shows the aggregate numbers of option awards (exercisable and unexercisable) held as of December 31, 2017 by each non-employee director who was serving as of December 31, 2017.

	<u>Options</u>
Name	Outstanding (#)
Name Thomas E. Shenk, Ph.D.	19,324
Keith R. Harris, Ph.D.	12,883
Ellen Hukkelhoven, Ph.D.	_
Arnold J. Levine, Ph.D.	6,441
Joel S. Marcus, J.D.	12,883
Neil Mendoza	12,883

In January 2018, our non-employee directors were granted options to purchase our ordinary shares in the following amounts: Mr. Shenk 23,189, Mr. Harris 23,189, Mr. Mendoza 15,459, Mr. Marcus 15,459 and Mr. Levine 15,459. The options vest in full on the first anniversary of the grant date.

Effective on the effective date of the registration statement of which this prospectus forms a part, we intend to adopt a compensation program for our non-employee directors under which each non-employee director will receive the following amounts for their services on our board of directors:

- an option to purchase 50,000 ordinary shares upon the director's initial election or appointment to our board of directors that occurs
  after our initial public offering;
- if the director has served on our board of directors for at least six months as of the date of an annual meeting of shareholders, and will continue to serve as a non-employee director immediately following such meeting, an option to purchase 25,000 ordinary shares on the date of the annual meeting;
- an annual director fee of \$25,000; and
- if the director serves on a committee of our board of directors or in the other capacities stated below, an additional annual fee as follows:
  - chairman of the board or lead independent director, \$25,000;

- chairman of the audit committee, \$15,000;
- audit committee member other than the chairman, \$5,000;
- chairman of the compensation committee, \$10,000;
- compensation committee member other than the chairman, \$5,000;
- i chairman of the nominating and corporate governance committee, \$10,000; and
- i nominating and corporate governance committee member other than the chairman, \$5,000.

Options granted to our non-employee directors under the program will have an exercise price equal to the fair market value of our ordinary shares on the date of grant and will expire not later than ten years after the date of grant. The options granted upon a director's initial election or appointment will vest in thirty-six (36) substantially equal monthly installments following the date of grant. The options granted annually to directors will vest in a single installment on the earlier of the day before the next annual meeting or the first anniversary of the date of grant. In addition, all unvested options will vest in full upon the occurrence of a change in control.

Director fees under the program will be payable in arrears in four equal quarterly installments not later than the fifteenth day following the final day of each calendar quarter, provided that the amount of each payment will be prorated for any portion of a quarter that a director is not serving on our board and no fee will be payable in respect of any period prior to the effective date of the registration statement of which this prospectus is a part.

#### **Incentive Plans**

The following summarizes the material terms of the long-term incentive compensation plan in which our named executive officers will be eligible to participate following the consummation of this offering and the 2016 Plan under which we have previously made periodic grants of equity and equity-based awards to our named executive officers and other key employees.

#### MeiraGTx Limited 2016 Equity Incentive Plan

Our board of directors approved the 2016 Plan under which we may grant non-qualified options, restricted stock, restricted stock units and other-stock based awards covering our ordinary shares. We had reserved a total of 1,621,360 ordinary shares for issuance under the 2016 Plan as of May 28, 2018.

Following the effectiveness of the 2018 Plan, we will not make any further grants under the 2016 Plan. However, the 2016 Plan will continue to govern the terms and conditions of the outstanding awards granted under it. Our ordinary shares subject to awards granted under the 2016 Plan that are forfeited, lapse unexercised or are settled in cash and which following the effective date of the 2018 Plan are not issued under the 2016 Plan will be available for issuance under the 2018 Plan.

Our board of directors administers the 2016 Plan and has the authority to take all actions and make all determinations under the 2016 Plan, and to adopt, amend and repeal rules for the administration of the 2016 Plan as it deems advisable. The board of directors may delegate its authority under the 2016 Plan to a committee of the board. Following the effectiveness of this offering, we expect that the board of directors will delegate its general administrative authority under the 2016 Plan to its compensation committee.

The 2016 Plan provides for the grant of non-qualified options, restricted stock, restricted stock units and other-stock based awards covering our ordinary shares to employees, directors and consultants of the company or its subsidiaries. As of the date of this prospectus, awards of options and restricted stock are outstanding under the 2016 Plan.

In connection with certain corporate transactions and events affecting our ordinary shares, including a change in control, or change in any applicable laws or accounting principles, the board of directors has broad

discretion to take action under the 2016 Plan to prevent the dilution or enlargement of intended benefits, facilitate the transaction or event or give effect to the change in applicable laws or accounting principles. In addition, in the event of certain non-reciprocal transactions with our shareholders, the board of directors will make equitable adjustments to outstanding awards under the 2016 Plan as it deems appropriate to reflect the transaction.

The board of directors may amend, suspend or terminate the 2016 Plan, or any portion thereof, at any time; provided that no amendment may materially and adversely affect an outstanding award without the consent of the affected participant.

#### 2018 Incentive Award Plan

Effective the day prior to the first public trading date of our ordinary shares, we have adopted and our shareholders have approved the 2018 Plan under which we may grant cash and equity-based incentive awards to eligible service providers in order to attract, retain and motivate the persons who make important contributions to our company. The material terms of the 2018 Plan are summarized below.

# Eligibility and Administration

Our employees, consultants and directors, and employees and consultants of our subsidiaries, will be eligible to receive awards under the 2018 Plan. The 2018 Plan will be administered by our board of directors, which may delegate its duties and responsibilities to one or more committees of our directors and/or officers (referred to collectively as the plan administrator below), subject to the limitations imposed under the 2018 Plan, Section 16 of the Exchange Act, stock exchange rules and other applicable laws. The plan administrator will have the authority to take all actions and make all determinations under the 2018 Plan, to interpret the 2018 Plan and award agreements and to adopt, amend and repeal rules for the administration of the 2018 Plan as it deems advisable. The plan administrator will also have the authority to determine which eligible service providers receive awards, grant awards and set the terms and conditions of all awards under the 2018 Plan, including any vesting and vesting acceleration provisions, subject to the conditions and limitations in the 2018 Plan.

#### Shares Available for Awards

An aggregate of 3,054,996 ordinary shares will initially be available for issuance under the 2018 Plan. The number of shares initially available for issuance will be increased by an annual increase on January 1 of each calendar year beginning in 2019 and ending in and including 2028, equal to the lesser of (A) 4% of the ordinary shares outstanding on the final day of the immediately preceding calendar year and (B) a smaller number of shares determined by our board of directors. No more than 16,547,897 ordinary shares may be issued under the 2018 Plan upon the exercise of incentive stock options. Shares issued under the 2018 Plan may be authorized but unissued shares, shares purchased on the open market or treasury shares.

If an award under the 2018 Plan or the 2016 Plan, expires, lapses or is terminated, exchanged for cash, surrendered, repurchased, canceled without having been fully exercised or forfeited, any unused shares subject to the award will, as applicable, become or again be available for new grants under the 2018 Plan. Awards granted under the 2018 Plan in substitution for any options or other share or share-based awards granted by an entity before the entity's merger or consolidation with us or our acquisition of the entity's property or stock will not reduce the shares available for grant under the 2018 Plan, but will count against the maximum number of shares that may be issued upon the exercise of incentive stock options.

# Awards

The 2018 Plan provides for the grant of options, including incentive stock options, or ISOs, and nonqualified stock options, or NSOs, share appreciation rights, or SARs, restricted shares, dividend equivalents, restricted share units, or RSUs, and other share or cash based awards. Certain awards under the 2018 Plan may

constitute or provide for payment of "nonqualified deferred compensation" under Section 409A of the Code. All awards under the 2018 Plan will be set forth in award agreements, which will detail the terms and conditions of awards, including any applicable vesting and payment terms and post-termination exercise limitations. A brief description of each award type follows.

- Options and SARs. Options provide for the purchase of our ordinary shares in the future at an exercise price set on the grant date. ISOs, by contrast to NSOs, may provide tax deferral beyond exercise and favorable capital gains tax treatment to their holders if certain holding period and other requirements of the Code are satisfied. SARs entitle their holder, upon exercise, to receive from us an amount equal to the appreciation of the shares subject to the award between the grant date and the exercise date. The plan administrator will determine the number of shares covered by each option and SAR, the exercise price of each option and SAR and the conditions and limitations applicable to the exercise of each option and SAR. The exercise price of an option or SAR will not be less than 100% of the fair market value of the underlying share on the grant date (or 110% in the case of ISOs granted to certain significant shareholders), except with respect to certain substitute awards granted in connection with a corporate transaction. The term of an option or SAR may not be longer than ten years (or five years in the case of ISOs granted to certain significant shareholders).
- Restricted Shares and RSUs. A restricted share is an award of nontransferable ordinary shares that remain forfeitable unless and until specified conditions are met and which may be subject to a purchase price. RSUs are contractual promises to deliver ordinary shares in the future, which may also remain forfeitable unless and until specified conditions are met and may be accompanied by the right to receive the equivalent value of dividends paid on ordinary shares prior to the delivery of the underlying shares. The plan administrator may provide that the delivery of the shares underlying RSUs will be deferred on a mandatory basis or at the election of the participant. The terms and conditions applicable to restricted shares and RSUs will be determined by the plan administrator, subject to the conditions and limitations contained in the 2018 Plan.
- Other Share or Cash Based Awards. Other share or cash based awards are awards of cash, fully vested ordinary shares and other awards valued wholly or partially by referring to, or otherwise based on, our ordinary shares or other property. Other share or cash based awards may be granted to participants and may also be available as a payment form in the settlement of other awards, as standalone payments and as payment in lieu of compensation to which a participant is otherwise entitled. The plan administrator will determine the terms and conditions of other share or cash based awards, which may include any purchase price, performance goal, transfer restrictions and vesting conditions.

#### Performance Criteria

The plan administrator may select performance criteria for an award to establish performance goals for a performance period. Performance criteria under the 2018 Plan may include, but are not limited to, the following: net earnings or losses (either before or after one or more of interest, taxes, depreciation, amortization, and non-cash equity-based compensation expense); gross or net sales or revenue or sales or revenue growth; net income (either before or after taxes) or adjusted net income; profits (including but not limited to gross profits, net profits, profit growth, net operation profit or economic profit), profit return ratios or operating margin; budget or operating earnings (either before or after taxes or before or after allocation of corporate overhead and bonus); cash flow (including operating cash flow and free cash flow or cash flow return on capital); return on assets; return on capital or invested capital; cost of capital; return on shareholders' equity; total shareholder return; return on sales; costs, reductions in costs and cost control measures; expenses; working capital; earnings or loss per share; adjusted earnings or loss per share; price per share or dividends per share (or appreciation in or maintenance of such price or dividends); regulatory achievements or compliance; implementation, completion or attainment of objectives relating to research, development, regulatory, commercial, or strategic milestones or developments; market share; economic value or economic value added models; division, group or corporate

financial goals; customer satisfaction/growth; customer service; employee satisfaction; recruitment and maintenance of personnel; human resources management; supervision of litigation and other legal matters; strategic partnerships and transactions; financial ratios (including those measuring liquidity, activity, profitability or leverage); debt levels or reductions; sales-related goals; financing and other capital raising transactions; cash on hand; acquisition activity; investment sourcing activity; and marketing initiatives, any of which may be measured in absolute terms or as compared to any incremental increase or decrease. Such performance goals also may be based solely by reference to the company's performance or the performance of a subsidiary, division, business segment or business unit of the company or a subsidiary, or based upon performance relative to performance of other companies or upon comparisons of any of the indicators of performance relative to performance of other companies. When determining performance goals, the plan administrator may provide for exclusion of the impact of an event or occurrence which the plan administrator determines should appropriately be excluded, including, without limitation, non-recurring charges or events, acquisitions or divestitures, changes in the corporate or capital structure, events unrelated to the business or outside of the control of management, foreign exchange considerations, and legal, regulatory, tax or accounting changes.

#### Certain Transactions

In connection with certain corporate transactions and events affecting our ordinary shares, including a change in control, or change in any applicable laws or accounting principles, the plan administrator has broad discretion to take action under the 2018 Plan to prevent the dilution or enlargement of intended benefits, facilitate the transaction or event or give effect to the change in applicable laws or accounting principles. This includes canceling awards for cash or property, accelerating the vesting of awards, providing for the assumption or substitution of awards by a successor entity, adjusting the number and type of shares subject to outstanding awards and/or with respect to which awards may be granted under the 2018 Plan and replacing or terminating awards under the 2018 Plan. In addition, in the event of certain non-reciprocal transactions with our shareholders, the plan administrator will make equitable adjustments to the 2018 Plan and outstanding awards as it deems appropriate to reflect the transaction.

#### Plan Amendment and Termination

Our board of directors may amend or terminate the 2018 Plan at any time; however, no amendment, other than an amendment that increases the number of shares available under the 2018 Plan, may materially and adversely affect an award outstanding under the 2018 Plan without the consent of the affected participant and shareholder approval will be obtained for any amendment to the extent necessary to comply with applicable laws. Further, the plan administrator cannot, without the approval of our shareholders, amend any outstanding option or SAR to reduce its price per share. The 2018 Plan will remain in effect until the tenth anniversary of its effective date, unless earlier terminated by our board of directors. No awards may be granted under the 2018 Plan after its termination.

Non-US Participants, Claw-Back Provisions, Transferability and Participant Payments

The plan administrator may modify awards granted to participants who are non-US nationals or employed outside the United States or establish subplans or procedures to address differences in laws, rules, regulations or customs of such jurisdictions outside the United States. All awards will be subject to any company claw-back policy as set forth in such claw-back policy or the applicable award agreement. Except as the plan administrator may determine or provide in an award agreement, awards under the 2018 Plan are generally non-transferrable, except by will or the laws of descent and distribution, or, subject to the plan administrator's consent, pursuant to a domestic relations order, and are generally exercisable only by the participant. With regard to tax withholding obligations arising in connection with awards under the 2018 Plan, and exercise price obligations arising in connection with the exercise of options under the 2018 Plan, the plan administrator may, in its discretion, accept cash, wire transfer or check, our ordinary shares that meet specified conditions, a promissory note, a "market sell order," such other consideration as the plan administrator deems suitable or any combination of the foregoing.

### 2018 Employee Share Purchase Plan

Effective the day prior to the first public trading date of our ordinary shares, we have adopted and our shareholders have approved the 2018 Employee Share Purchase Plan, or the 2018 ESPP. The material terms of the 2018 ESPP are summarized below.

Shares Available for Awards; Administration

A total of 509,166 ordinary shares will initially be reserved for issuance under the 2018 ESPP. In addition, the number of shares available for issuance under the 2018 ESPP will be annually increased on January 1 of each calendar year beginning in 2019 and ending in and including 2028, by an amount equal to the lesser of (A) 1% of the shares outstanding on the final day of the immediately preceding calendar year and (B) such smaller number of shares as is determined by our board of directors, provided that no more than 3,818,745 ordinary shares may be issued under the 2018 ESPP. The foregoing numbers are subject to adjustment in certain events, as described below. Our board of directors or a committee of our board of directors will have authority to interpret the terms of the 2018 ESPP and determine eligibility of participants. We expect that the compensation committee will be the initial administrator of the 2018 ESPP.

Eligibility

Our employees are eligible to participate in the 2018 ESPP if they are customarily employed by us or a participating subsidiary for more than twenty hours per week and more than five months in any calendar year. However, an employee may not be granted rights to purchase shares under our 2018 ESPP if the employee, immediately after the grant, would own (directly or through attribution) shares possessing 5% or more of the total combined voting power or value of all classes of our shares.

**Grant of Rights** 

The 2018 ESPP is intended to qualify under Section 423 of the Code and shares will be offered under the 2018 ESPP during offering periods. The length of the offering periods under the 2018 ESPP will be determined by the plan administrator and may be up to twenty-seven months long. Employee payroll deductions will be used to purchase shares on each purchase date during an offering period. The purchase dates for each offering period will be the final trading day in the offering period. Offering periods under the 2018 ESPP will commence when determined by the plan administrator. The plan administrator may, in its discretion, modify the terms of future offering periods.

The 2018 ESPP permits participants to purchase ordinary shares through payroll deductions of up to 25% of their eligible compensation, which includes a participant's gross base compensation for services to us, including overtime payments and excluding sales commissions, incentive compensation, bonuses, expense reimbursements, fringe benefits and other special payments. The plan administrator will establish a maximum number of shares that may be purchased by a participant during any offering period, which, in the absence of a contrary designation, will be 25,000 shares. In addition, no employee will be permitted to accrue the right to purchase shares under the 2018 ESPP at a rate in excess of \$25,000 worth of shares during any calendar year during which such a purchase right is outstanding (based on the fair market value per share of our ordinary shares as of the first day of the offering period).

On the first trading day of each offering period, each participant will automatically be granted an option to purchase our ordinary shares. The option will expire at the end of the applicable offering period, and will be exercised at that time to the extent of the payroll deductions accumulated during the offering period. The purchase price of the shares, in the absence of a contrary designation, will be 85% of the lower of the fair market value of our ordinary shares on the first trading day of the offering period or on the purchase date. Participants may voluntarily end their participation in the 2018 ESPP at any time at least one week prior to the end of the

applicable offering period, and will be paid their accrued payroll deductions that have not yet been used to purchase ordinary shares. Participation ends automatically upon a participant's termination of employment.

A participant may not transfer rights granted under the 2018 ESPP other than by will or the laws of descent and distribution.

#### Certain Transactions

In the event of certain non-reciprocal transactions or events affecting our ordinary shares known as "equity restructurings," the plan administrator will make equitable adjustments to the 2018 ESPP and outstanding rights. In the event of certain unusual or non-recurring events or transactions, including a change in control, the plan administrator may provide for (1) either the replacement of outstanding rights with other rights or property or termination of outstanding rights in exchange for cash, (2) the assumption or substitution of outstanding rights by the successor or survivor corporation or parent or subsidiary thereof, if any, (3) the adjustment in the number and type of shares subject to outstanding rights, (4) the use of participants' accumulated payroll deductions to purchase shares on a new purchase date prior to the next scheduled purchase date and termination of any rights under ongoing offering periods or (5) the termination of all outstanding rights.

#### Plan Amendment

The plan administrator may amend, suspend or terminate the 2018 ESPP at any time. However, shareholder approval will be obtained for any amendment that increases the aggregate number or changes the type of shares that may be sold pursuant to rights under the 2018 ESPP, changes the corporations or classes of corporations whose employees are eligible to participate in the 2018 ESPP or changes the 2018 ESPP in any manner that would cause the 2018 ESPP to no longer be an employee stock purchase plan within the meaning of Section 423(b) of the Code.

#### CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following includes a summary of transactions since January 1, 2015 to which we have been a party in which the amount involved exceeded or will exceed \$120,000, and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our share capital or any member of the immediate family of any of the foregoing persons had, or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control and other arrangements, which are described under "Executive and Director Compensation." We also describe below certain other transactions with our directors, executive officers and shareholders.

#### **Preferred and Ordinary Share Financings**

### Series C Preferred Shares

From October 2015 through April 2018, we issued an aggregate 10,172,835 Series C preferred shares at a purchase price of \$10.48 per share, for aggregate consideration of approximately \$106.6 million, to investors.

From April 2016 to September 2017, we issued an aggregate 118,526 Series C preferred shares to Kadmon Corporation, LLC, or Kadmon, with an aggregate value of approximately \$1.2 million as partial payment of amounts owed under the transition services agreement, or Kadmon TSA. See "—Kadmon Transition Services Agreement" for additional information.

In May 2017, we issued a convertible note to an entity affiliated with Alexandria Equities, No. 7, LLC, or Alexandria, in the principal amount of \$2.5 million and an interest rate of 10% per annum, or the Convertible Note. In November 2017, we issued 238,579 Series C preferred shares to Alexandria, with an aggregate value of approximately \$2.5 million, upon conversion of the Convertible Note in satisfaction of the full principal. In accordance with the terms of the Convertible Note, the accrued interest in an amount of \$0.1 million was cancelled.

#### Warrants

In September 2017, we issued a warrant to Perceptive Life Sciences Master Fund, Ltd., to purchase 695,696 of our Series C preferred shares at an exercise price of \$10.48, which was valued under the Black- Scholes pricing model at approximately \$1.7 million.

In November 2017, we issued a warrant to Alexandria to purchase 231,898 Series C preferred shares at an exercise price of \$10.48, which was valued under the Black-Scholes pricing model at approximately \$0.6 million, as an inducement to convert the Convertible Note described above.

### Series A Ordinary Shares

In April 2015, we issued an aggregate of 1,050,831 Series A ordinary shares of purchase prices of \$7.76 and \$13.58 per share, for an aggregate consideration of approximately \$8.7 million to investors and an aggregate of 5,611,791 Series A ordinary shares for nominal consideration to our founders.

The following table sets forth the aggregate number of Series A ordinary shares, Series C preferred shares and warrants to purchase Series C preferred shares acquired by directors and officers and beneficial owners of more than 5% of our shares in the financing transactions described above.

	Series A	<u>Series C</u> <u>Preferred</u>	
Participants 1.000	Ordinary Shares	Shares	Warrants
Directors and Officers			
Alexandria Forbes†	855,673	_	_
Richard Giroux†	571,829	_	_
Stuart Naylor	510,900	_	_
Thomas Shenk	170,809	_	_
Gregory S. Moss	41,285	_	_
Joel S. Marcus	32,208	47,714	_
Neil Mendoza	12,883	_	_
5% or Greater Shareholders(1)	_	_	_
Kadmon Corporation, LLC	3,416,181	118,526	_
Perceptive Life Sciences Master Fund, Ltd	<del>-</del>	2,624,369	695,696
Adena Estate, Inc.	322,081	1,431,475	_
Alexandria Equities No. 7, LLC	96,495	1,321,000	231,898
Robin Ali, Ph.D.†	1,094,255	_	_

<sup>(1)</sup> Additional details regarding these shareholders and their equity holdings are provided in this prospectus under the caption "Principal Shareholders."

Some of our directors are associated with our principal shareholders as indicated in the table below:

Director
Alexandria Forbes
Thomas E. Shenk
Gregory S. Moss
Ellen Hukkelhoven
Joel S. Marcus

Principal Shareholder
Kadmon Corporation, LLC
Kadmon Corporation, LLC
Kadmon Corporation, LLC
Redmon Corporation, LLC
Perceptive Life Sciences Master Fund, Ltd
Alexandria Equities No. 7, LLC

Drs. Forbes and Shenk will resign from the board of directors of Kadmon Holdings, Inc. effective upon the effectiveness of this registration statement of which this prospectus forms a part.

### License Agreements

In February 2015, Athena Vision Ltd., an entity acquired in April 2016, entered into a license agreement with UCL Business, PLC, or UCLB, which was amended in March 2015, July 2017 and December 2017. See "Business—Licensed Intellectual Property."

In May 2013, BRI-Alzan Inc. entered into a license agreement that was assigned to us as a result of our subsequent merger with BRI-Alzan Inc. in 2015. See "Business—Licensed Intellectual Property."

## **Employment Agreements**

We have entered into employment agreements with our named executive officers. For more information regarding the agreements with our named executive officers, see "Executive and Director Compensation—Executive Compensation Arrangements."

In April 2015, we entered into a service agreement with Robin Ali, a greater than 5% holder of our ordinary shares. On April 24, 2015, we granted Dr. Ali pursuant to the service agreement 448,157 Series A ordinary

shares. Under the terms of the agreement, Dr. Ali will receive aggregate compensation of £110,000 per year, or approximately \$146,000 using average exchange rates as of December 31, 2017. The agreement may be terminated at any time by either party by giving twelve-months' notice. For the years ended December 31, 2015, 2016 and 2017, the Company recorded £110,000, £110,000 and £110,000 or approximately \$162,000, \$135,000 and \$128,000, respectively, using the average exchange rates during the year ended December 31, 2015, 2016 and 2017, respectively, in research and development costs under these agreements. Future obligations to be paid under this agreement equal £110,000, or approximately \$149,000, using exchange rates as of December 31, 2017.

In April 2015, we entered into a service agreement with Stuart Naylor, one of our officers and directors. On April 24, 2015, we granted Mr. Naylor pursuant to the service agreement 248,969 Series A ordinary shares. For further information, see "Executive and Director Compensation—Executive Compensation Arrangements.

### **Consulting Agreements**

We and Samuel D. Waksal, Ph.D., a holder of 7.8% of our outstanding equity at the time of our formation in March 2015, and therefore a "related person" under Item 404 of Regulation S-K, entered into a consulting agreement on April 24, 2015 that was subsequently renewed on January 1, 2016, January 1, 2017 and January 1, 2018. Pursuant to the terms of the consulting agreement, we paid Dr. Waksal compensation for his consulting services of \$750,000, \$850,000 and \$850,000 for each of the years ended December 31, 2015, December 31, 2016, and December 31, 2017, respectively. Effective on May 14, 2018, we terminated Dr. Waksal's agreement, and pursuant to its terms, we have agreed to pay him compensation of \$197,260 for services performed during 2018. In addition, on March 4, 2016 and September 20, 2017, Dr. Waksal was granted options to purchase 51,533 and 77,299 ordinary shares, respectively, at exercise prices of \$7.72 and \$2.64, respectively. In 2002, Dr. Waksal was charged by the SEC with violating the federal securities laws in connection with trades made in the shares of ImClone Systems Incorporated, where he served as president and chief executive officer and as a director. Dr. Waksal was also charged with, and subsequently pled guilty to, securities fraud, bank fraud, wire fraud, obstruction of justice, perjury and related conspiracy charges. He is subject to a final judgment and order on consent that permanently bars him from acting as an officer or director of any public company. As of April 30, 2018, Dr. Waksal held shares representing approximately 2.9% of our outstanding equity. Upon completion of this offering, Dr. Waksal will hold shares representing approximately 2.2% of our outstanding equity, assuming that we sell the number of shares set forth on the cover page of this prospectus in this offering.

Effective September 28, 2015, we entered into a three-year consulting agreement with Thomas Shenk, Ph.D., one of our directors. In connection with the agreement, we issued Dr. Shenk 170,809 Series A ordinary shares for aggregate consideration of \$1.3 million. Under the consulting agreement, such shares are subject to forfeiture ratably over a period of three years if Dr. Shenk does not remain a consultant to us.

### **Indications of Interest to Participate in this Offering**

Certain of our existing shareholders and their affiliated entities have indicated an interest in purchasing an aggregate of up to approximately \$40.0 million of our ordinary shares in this offering at the initial public offering price per share and on the same terms as the other purchasers in this offering. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could determine to sell more, fewer or no shares to any of these potential purchasers, and any of these potential purchasers could determine to purchase more, fewer or no shares in this offering.

## **Indemnification Agreements**

We intend to enter into indemnification agreements with each of our directors and executive officers. These agreements, among other things, require us or will require us to indemnify each director (and in certain cases their related investment funds) and executive officer against all expenses such as attorneys' fees,

judgments, penalties, fines and amounts paid in settlement actually and reasonably incurred by the director or executive officer or on his behalf, in connection with such proceeding or any claim, issue or matter therein, if the person acted in good faith and in a manner the person reasonably believed to be in or not opposed to the best interests of our company, and with respect to any criminal proceeding, had no reasonable cause to believe the person's conduct was unlawful. For further information, see "Executive and Director Compensation—Limitations of Liability and Indemnification."

### **Share Option and Restricted Share Grants to Executive Officers and Directors**

We have granted share options and restricted shares to our executive officers and certain of our directors as more fully described in the section entitled "Executive and Director Compensation."

### **Kadmon Transition Services Agreement**

In April 2015, we entered into the Kadmon TSA to provide us with office and laboratory facilities, as well as personal support activities. Under the agreement, we are charged for (i) rent based upon the square footage of the office and laboratory facilities we use, (ii) other personnel support activities based upon hours of the personnel providing the support activities, and (iii) other direct costs incurred by Kadmon on our behalf, plus a 7% administrative fee. We made cash payments under the agreement of \$225,078 and \$275,941 during the years ended December 31, 2016 and 2017, respectively. During the three-month periods ended March 31, 2017 and 2018, we made cash payments to Kadmon totaling \$275,941 and \$997,417, respectively. From April 2016 to September 2017, we issued an aggregate 118,526 Series C preferred shares to Kadmon in aggregate amount of \$1,242,000 as partial payment of amounts owed under the agreement. As of December 31, 2016 and 2017 and March 31, 2018, the amount due to Kadmon was \$543,038, \$861,030 and \$6,493, respectively. Either party may terminate the agreement upon 30-days' notice. The Kadmon TSA terminated on April 24, 2018.

#### **Moorfields Lease**

In February 2016, we entered into a five-year lease with Moorfields Eye Hospital, NHS Foundation Trust and Kadmon, a greater than 5% shareholder. Under the lease, Kadmon is a guarantor of our rent obligations and has agreed to indemnify Moorfields as the landlord against any failure by the tenant to pay the rent or otherwise perform its obligations thereunder.

### **UCL Agreements**

#### Services Agreement

In October 2016, we entered into a four-year services agreement with UCL Consultants Limited, an entity affiliated with UCLB. One of our shareholders, Robin Ali, is a professor at University College London, or UCL, an entity affiliated with UCLB and UCL Consultants Limited. Under the agreement, UCL Consultants Limited provides pre-clinical research and development services under our direction. In connection with the agreement, we issued several work orders during the years ended December 31, 2016 and 2017 in aggregate amounts of \$1,574,000 and \$311,000, respectively. The total research and development expenses for the years ended December 31, 2016 and 2017 were approximately \$278,000 and \$538,000, respectively. Future obligations under the agreement are approximately \$1,438,869. As of the years ended December 31, 2016 and 2017, the amount due to UCL was \$251,754 and \$775,315, respectively. Either party may terminate the agreement upon 30-days written notice.

### **Manufacturing and Supply Agreement**

In September 2016, we entered into a manufacturing and drug supply agreement with UCL to manufacture materials for our clinical trials under our direction, which was terminated in January 2018. The total

research and development expenses for the years ending December 31, 2016 and 2017 were \$456,106 and \$1,904,352, respectively. As of the years ended December 31, 2016 and 2017, the amount due to UCL was \$412,395 and \$2,466,142, respectively.

#### **ARE Leases**

### July 2016 Lease

Effective July 2016, we entered into a non-cancellable operating lease for laboratory facilities in New York with ARE-East River Science Park, LLC, or ARE, an entity affiliated with Alexandria and Joel S. Marcus, Executive Chairman of Alexandria Real Estate Equities, Inc. Under the lease, we pay monthly base rent, property management fees and operating expenses for the duration of the lease term, which expires in December 2021. The total rent expense under the lease for the years ended December 31, 2016 and 2017 was \$243,780 and \$487,559, respectively. In July 2016, in connection with the signing of the lease, we entered into a standby letter of credit agreement for \$122,866, which serves as a security deposit for the premises. The standby letter of credit expires on is automatically renewed annually through July 7, 2021. As of the years ended December 31, 2016 and 2017, the balance of deferred rent was \$243,780 and \$231,276, respectively. Aggregate future minimum rental payments under the lease are \$2,181,520 as of December 31, 2017.

#### December 2016 Lease

In December 2016, we entered into a non-cancellable operating lease for laboratory and office facilities in New York with ARE expiring in October 2032. Under the lease, we pay monthly base rent, property management fees, and operating expenses during the lease term. In December 2016, in connection with the signing of the lease, we entered into a standby letter of credit agreement for \$321,977, which served as a security deposit for the premises. The standby letter of credit was cancelled on November 2017. In October 2017, the lease was amended whereby the lease would terminate on March 2018 and only base rent and management fees in the aggregate amount of \$563,507 would be due for the period from November 2017 through March 2018. Under the amendment, we issued a promissory note in the principal amount of \$1,442,009 to ARE at an interest rate of 5% per annum, which removed the balance of the deferred rent and accrued the future rent payments. The note is due on December 31, 2018, however, the note and accrued interest will become due and payable if we achieve sufficient liquidity as defined in the note. If we do not have sufficient liquidity, which is defined as our cash, cash equivalents and liquid short-term investments of at least an investment grade are at least 20 times greater than the note plus accrued interest, prior to the due date, we may repay the note in either cash or Series C preferred shares. We recorded an interest expense in the amount of \$13,037 for the year ended December 31, 2017. The total rent expense under the operating lease was \$43,578 and \$1,660,806 for the years ended December 31, 2016 and 2017 respectively. As of the years ended December 31, 2016 and 2017, the balance of deferred lease obligation was \$11,380 and \$0 respectively. Aggregate future minimal rental payments under the lease are \$332,442 as of December 31, 2017.

### **Shareholder Agreement**

Upon consummation of the Corporate Reorganization, we will enter into a Shareholder Agreement with our shareholders, including Alexandria Forbes, Richard Giroux, Stuart Naylor, Joel S. Marcus, Thomas Shenk, Keith Harris, Arnold Levine, Kadmon Corporation, LLC, Perceptive Life Sciences Master Fund, Ltd., Adena Estate, Inc., Alexandria Equities No. 7, LLC. and Robin Ali. The Shareholder Agreement, other than provisions related to registration rights, confidentiality, rights of third parties and governing law, will terminate upon consummation of our initial public offering. Provisions related to registration rights will terminate upon the earlier to occur of a deemed liquidation event, such time as Rule 144 or another similar exemption under the Securities Act is available for the sale of a holder's shares without limitation during a three-month period without registration, and the third anniversary of our initial public offering. See "Description of Share Capital and Articles of Association-Registration Rights" for additional information.

### **Policies and Procedures for Related Person Transactions**

Our board of directors has adopted a written related person transaction policy, to be effective upon the closing of this offering, setting forth the policies and procedures for the review and approval or ratification of related person transactions. This policy will cover, with certain exceptions set forth in Item 404 of Regulation S-K under the Securities Act, any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we were or are to be a participant, where the amount involved exceeds \$5,000 in any fiscal year and a related person had, has or will have a direct or indirect material interest, including without limitation, purchases of goods or services by or from the related person or entities in which the related person has a material interest, indebtedness, guarantees of indebtedness and employment by us of a related person. In reviewing and approving any such transactions, our audit committee is tasked to consider all relevant facts and circumstances, including, but not limited to, whether the transaction is on terms comparable to those that could be obtained in an arm's length transaction and the extent of the related person's interest in the transaction. All of the transactions described in this section occurred prior to the adoption of this policy.

#### PRINCIPAL SHAREHOLDERS

The following table sets forth information with respect to the beneficial ownership of our ordinary shares, as of April 30, 2018, (i) immediately prior to this offering, and (ii) after giving effect to the offering:

- each person or group of affiliated persons known by us to beneficially own more than 5% of our ordinary shares;
- each of our named executive officers;
- · each of our directors; and
- all of our executive officers and directors as a group.

The number of shares beneficially owned by each shareholder is determined under rules issued by the Securities and Exchange Commission. Under these rules, beneficial ownership includes any shares as to which the individual or entity has sole or shared voting power or investment power. Applicable percentage ownership is based on 27,184,140 ordinary shares outstanding as of April 30, 2018, after giving effect to our Corporate Reorganization, the conversion of the preferred shares, including preferred shares issued in connection with the exercise of warrants, into ordinary shares prior to the closing of this offering, and, solely in the case of beneficial ownership after giving effect to the offering, the Executive IPO Grants. In computing the number of shares beneficially owned by an individual or entity and the percentage ownership of that person, ordinary shares subject to options, warrants or other rights held by such person that are currently exercisable or will become exercisable within 60 days of April 30, 2018 are considered outstanding, although these shares are not considered outstanding for purposes of computing the percentage ownership of any other person. Unless noted otherwise, the address of all listed shareholders is 430 E. 29th Street, 10th Floor, New York, New York 10016. Each of the shareholders listed has sole voting and investment power with respect to the shares beneficially owned by the shareholder unless noted otherwise, subject to community property laws where applicable.

Certain of our existing shareholders and their affiliated entities have indicated an interest in purchasing an aggregate of up to approximately \$40.0 million of our ordinary shares in this offering at the initial public offering price per share and on the same terms as the other purchasers in this offering. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could determine to sell more, fewer or no shares to any of these potential purchasers, and any of these potential purchasers could determine to purchase more, fewer or no shares in this offering. The following table does not reflect any potential purchases by these potential purchasers. If any shares are purchased by our existing shareholders or their affiliated entities, the number and percentage of ordinary shares beneficially owned by them after this offering will differ from those set forth in the following table.

	<u>Shares Benefi</u> Prior to		<u>Shares Benefi</u> After O	
Name of Beneficial Owner	Number	Percentage _	Number Number	Percentage Percentage
5% or Greater Shareholders				
Kadmon Corporation, LLC(1)	3,534,707	16.9%	3,534,707	13.0%
Perceptive Life Sciences Master Fund, Ltd(2)	3,320,065	15.9	3,320,065	12.2
Adena Estate, Inc.(3)	1,753,556	8.4	1,753,556	6.5
Alexandria Equities No. 7, LLC(4)	1,649,393	7.9	1,649,393	6.1
Robin Ali, Ph.D.	1,094,255	5.2	1,094,255	4.0
Named Executive Officers and Directors				
Keith R. Harris, Ph.D.(5)	12,883	*	12,883	*
Alexandria Forbes, Ph.D.(6)	889,714	4.3	1,542,888	5.7
Ellen Hukkelhoven, Ph.D.	_	_	_	_
Arnold J. Levine, Ph.D.(7)	6,441	*	6,441	*
Joel S. Marcus(8)	1,742,198	8.3	1,742,198	6.4
Neil Mendoza(9)	25,766	*	25,766	*
Gregory S. Moss	41,285	*	41,285	*
Stuart Naylor, Ph.D.(10)	512,509	2.5	512,509	1.9
Thomas E. Shenk, Ph.D.(11)	190,133	*	190,133	*
Richard Giroux(12)	599,366	2.9	1,252,540	4.6
All executive officers and directors as a group (10 persons)(13)	4,020,295	19.1	5,326,643	19.5

- Less than 1%
- The sole member of Kadmon Corporation, LLC is Kadmon Holdings, Inc. Alexandria Forbes and Thomas Shenk, two of our directors, are also directors of Kadmon Holdings, Inc. and Gregory S. Moss, one of our directors, is Senior Vice President, Deputy General Counsel of Kadmon Holdings, Inc. Drs. Forbes and Shenk will resign from the board of directors of Kadmon Holdings, Inc. effective upon the effectiveness of this registration statement. The address of Kadmon Corporation, LLC is 450 E. 29th Street, 16th Floor, New York, New York
- Includes a warrant to purchase 695,696 ordinary shares that is or will be immediately exercisable within 60 days of April 30, 2018 held by Perceptive Life Sciences Master Fund, Ltd. Ellen Hukkelhoven, one of our directors, is a senior analyst at Perceptive Advisors, LLC, which is the investment manager of Perceptive Life Sciences Master Fund, Ltd. The address of Perceptive Life Sciences Master Fund, Ltd. is c/o Perceptive Advisors LLC, 51 Astor Place, 10th Floor, New York, New York 10003.

  The address of Adena Estate, Inc. is Craigmuir Chambers, P.O. Box 71, Road Town, Tortola, VG1110, British Virgin Islands.

  Includes a warrant to purchase 231,898 ordinary shares. The address for Alexandria Equities No. 7, LLC is 385 E. Colorado Blvd., Suite 299, Pasadena, California 91101. One of our
- directors, Joel S. Marcus, is the Executive Chairman of ARE-QRS Corp., the general partner of Alexandria Real Estate Equities L.P., which is the managing member of Alexandria Equities No. 7, LLC.

  Consists of options to purchase 12,883 ordinary shares that are or will be immediately exercisable within 60 days of April 30, 2018.

  Consists of 855,673 ordinary shares and options to purchase 34,041 ordinary shares that are or will be immediately exercisable within 60 days of April 30, 2018. In addition, shares beneficially owned after offering reflects 217,725 vested shares and 435,449 unvested shares granted upon effectiveness of this registration statement as part of the Execution IPO

- Consists of options to purchase 6,441 ordinary shares that are or will be immediately exercisable within 60 days of April 30, 2018.

  Includes a warrant to purchase 231,898 ordinary shares held by Alexandria Equities No. 7, LLC, 79,922 ordinary shares held by Third Amended and Restated Joel and Barbara Marcus Family Trust and options held by Joel S. Marcus to purchase 12,883 ordinary shares that are or will be immediately exercisable within 60 days of April 30, 2018. Joel Marcus, one of our directors, is the Executive Chairman of ARE-QRS Corp., the general partner of Alexandria Real Estate Equities L.P., which is the managing member of Alexandria Equities No. 7, LLC. ARE-QRS Corp., the general partner of Alexandria Real Estate Equities L.P., which is the managing member of Alexandria Equities No. 7, LLC. ARE-QRS Corp. has full voting and investment power with respect to the shares owned by Alexandria Equities No. 7, LLC. As Executive Chairman of ARE-QRS Corp., Mr. Marcus may be deemed to have voting and investment power with respect to the shares owned by Alexandria Equities No. 7, LLC. Mr. Marcus disclaims beneficial ownership of the shares held by Alexandria Equities No. 7, LLC, except to the extent of his underlying pecuniary interest therein. Includes options to purchase 12,883 ordinary shares that are or will be immediately exercisable within 60 days of April 30, 2018.
- Includes options to purchase 14,492 ordinary shares that are or will be immediately exercisable within 60 days of April 30, 2018.
- Consists of 170,809 ordinary shares held by Double Epiphany, LLC and options held by Thomas Shenk to purchase 19,324 ordinary shares that are or will be immediately exercisable within 60 days of April 30, 2018. The managing members of Double Epiphany, LLC are Thomas E. Shenk and Lillian W. Chiang, who have full voting and investment power with respect to the shares held by Double Epiphany, LLC. The address for Double Epiphany, LLC is 12 Boudinot Street, Princeton, New Jersey 08540. Includes options to purchase 27,537 ordinary shares that are or will be immediately exercisable within 60 days of April 30, 2018. In addition, shares beneficially owned after offering reflects 217,725 vested shares granted and 435,449 unvested shares granted upon effectiveness of this registration statement as part of the Execution IPO Grants.
- Includes a warrant to purchase 231,898 ordinary shares and options to purchase 140,484 ordinary shares that are or will be immediately exercisable within 60 days of April 30, 2018.

#### DESCRIPTION OF SHARE CAPITAL AND ARTICLES OF ASSOCIATION

The following describes the issued share capital of MeiraGTx Holdings plc (the "Issuer"), summarizes the material provisions of the articles of association of the Issuer as are anticipated to be in effect upon the completion of this offering and highlights certain differences in corporate law in the Cayman Islands and Delaware, the United States. In this "Description of Share Capital and Articles of Association" discussion, we use the term "we," "us" and "our" to refer to the Issuer.

#### General

We were incorporated pursuant to the laws of the Cayman Islands as an exempted company with limited liability to become the holding company of our business. Pursuant to the terms of our corporate reorganization, which will be completed prior to the completion of this offering, all of the issued share capital in MeiraGTx Limited will be exchanged for shares in the Issuer and, as a result, MeiraGTx Limited will become a wholly owned subsidiary of the Issuer. See "Corporate Reorganization" for more information.

The principal legislation under which the Issuer will operate and its shares will be issued is the Cayman Islands Companies Law (2018 Revision) (the "Companies Law").

Our register of shareholders will be maintained by Computershare Trust Company N.A.

Following our Corporate Reorganization, certain resolutions will be required to be passed by our shareholders prior to the completion of this offering. These will include resolutions for the:

- · adoption of new articles of association that will become effective upon the completion of this offering; and
- reorganization of the share capital of the Issuer.

#### **Share Capital**

Upon completion of the Corporate Reorganization, the conversion of the preferred shares into ordinary shares, including preferred shares issued in connection with the exercise of warrants, and the effectiveness of a 1 for 3.881 reverse share split (by way of consolidation of the share capital of the Company), the authorized share capital of MeiraGTx Holdings plc will consist of \$50,000 divided into 1,288,327,750 shares, nominal value \$0.0003881 per share. Upon completion of the Corporate Reorganization, the conversion of the preferred shares into ordinary shares, including preferred shares issued in connection with the exercise of warrants, the effectiveness of a 1 for 3.881 reverse share split (by way of consolidation of the share capital of the Company), and the issuance of the Executive IPO Grants, there will be 22,184,140 ordinary shares issued and outstanding. As of April 30, 2018, after giving effect to the Corporate Reorganization, the exercise of all outstanding warrants, and the conversion of the preferred shares into ordinary shares, there were 74 holders of record.

### **Ordinary Shares**

### General

All of our issued and outstanding ordinary shares are fully paid and non assessable. Certificates representing our issued and outstanding ordinary shares are generally not issued and legal title to our issued shares is recorded in registered form in the register of members. Holders of our ordinary shares have no preemptive, subscription, redemption or conversion rights.

Our board of directors may provide for other classes of shares, including classes of preferred shares, out of our authorized but unissued share capital, which could be utilized for a variety of corporate purposes, including future offerings to raise capital for corporate purposes or for use in employee benefit plans. Such additional classes of shares shall have such rights, restrictions, preferences, privileges and payment obligations as determined by our board of directors. If we issue any preferred shares, the rights, preferences and privileges of holders of our ordinary shares will be subject to, and may be adversely affected by, the rights of the holders of such preferred shares. See "—Variation of rights."

#### **Dividends**

The holders of our ordinary shares are entitled to such dividends as may be declared by our board of directors subject to the Companies Law and our amended and restated memorandum and articles of association. Dividends and other distributions on issued and outstanding ordinary shares may be paid out of the funds of the Issuer lawfully available for such purpose, subject to any preference of any outstanding preferred shares. Dividends and other distributions will be distributed among the holders of our ordinary shares on a pro rata basis.

#### Voting rights

Voting at any shareholders' meeting is by show of hands, unless voting by way of poll demanded by the chairman of the board of directors or any shareholder present or voting by proxy. On a show of hands every shareholder present in person or by proxy shall have one vote and on a poll every shareholder present in person or by proxy shall have one vote for each ordinary share on all matters upon which the ordinary shares are entitled to vote.

A quorum required for a meeting of shareholders consists of holders with at least one-third of the votes eligible to be cast at any such general meeting of the Issuer.

An ordinary resolution to be passed by the shareholders requires the affirmative vote of a simple majority of the votes attaching to the ordinary shares cast in a general meeting, while a special resolution requires the affirmative vote of not less than two thirds of the votes attaching to the ordinary shares cast in a general meeting. An ordinary resolution or a special resolution may also be adopted by way of unanimous written resolution signed by or on behalf of each shareholder who would have been entitled to vote on such matter at a general meeting without a meeting being held. A special resolution will be required for matters such as certain merger or consolidation transactions, the change of name of the Issuer, making changes to our amended and restated memorandum and articles of association, or the voluntary winding up of the Issuer.

#### Variation of rights

The rights attached to any class of shares (unless otherwise provided by the terms of issue of that class), such as voting, dividends and the like, may be varied only with the sanction of a resolution passed by not less than two-thirds of the votes attaching to the shares of the relevant class cast in a meeting of the holders of the shares of that class, or by the written consent of the holders of not less than two-thirds of the shares of that class. The rights conferred upon the holders of the shares of any class shall not (unless otherwise provided by the terms of issue of that class) be deemed to be varied by the creation or issue of further shares ranking in priority to or pari passu with such previously existing shares.

### Transfer of ordinary shares

Any of our shareholders may transfer all or any of his or her ordinary shares by an instrument of transfer in the usual or common form or any other form approved by our board of directors, subject to the applicable restrictions of our amended and restated memorandum and articles of association which will become effective upon the completion of this offering, such as the suspension of transfers for a period immediately preceding a general meeting, or the determination that a proposed transfer is not eligible.

### Liquidation

On a return of capital on winding up or otherwise (other than on conversion, redemption or purchase of ordinary shares), assets available for distribution among the holders of ordinary shares shall be distributed among the holders of the ordinary shares on a pro rata basis.

### Directors

The management of our company is vested in our board of directors. The quorum necessary for any meeting of our board of directors shall consist of at least a majority of the members of our board of directors and questions arising at any meeting shall be decided by a majority of votes.

Our amended and restated memorandum and articles of association, which will become effective upon completion of this offering, provide that our board of directors will be divided into three classes with staggered, three-year terms. At each annual meeting of shareholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election. The election of directors shall be by a plurality of the votes of the shares entitled to vote on the election of directors.

In addition, subject to the maximum number of directors designated by resolution of the board of directors, additional directors may be appointed from time to time by the board of Directors or by ordinary resolution either as a result of a casual vacancy or as an additional director.

Directors may be removed or replaced by an ordinary resolution of the shareholders.

### **Indemnity of directors and officers**

Our amended and restated memorandum and articles of association provide that our board of directors and officers shall be indemnified from and against all liability which they incur in execution of their duty in their respective offices, except liability incurred by reason of such director's or officer's dishonesty, willful default or fraud.

### **Registration Rights**

Holders of Series C preferred shares, as of the effectiveness of the Corporate Reorganization, who hold not less than 3% of the fully diluted share capital of the Company, and certain other holders will be entitled to certain rights with respect to the registration of ordinary shares for public resale under the Securities Act, pursuant to a Shareholder Agreement by and among us and certain of our shareholders. After giving effect to the conversion of the preferred shares into ordinary shares, holders of an aggregate of 16,123,234 ordinary shares will have these rights. These rights terminate upon the earlier to occur of a deemed liquidation event, such time as Rule 144 or another similar exemption under the Securities Act is available for the sale of a holder's shares without limitation during a three-month period without registration, and the third anniversary of our initial public offering. The registration of ordinary shares as a result of these rights being exercised would enable holders to trade these shares without restriction under the Securities Act when the applicable registration statement is declared effective.

Subject to certain exceptions, including this offering, if we propose to register any of our ordinary shares in connection with a public offering of such securities solely for cash, we are obligated to notify the eligible holders of such registration. Upon the request of any such eligible holders given within 20 days following the registration notice, we are obligated, subject to certain exceptions, to register all of the ordinary shares then owned by the eligible holder that such holder has requested to be included in such registration. If the holders requesting registration intend to distribute their shares by means of an underwriting, the underwriters of such offering will have the right to limit the numbers of shares to be underwritten for reasons related to the marketing of the shares.

## **Differences in Corporate Law**

Cayman Islands companies are governed by the Companies Law. The Companies Law is modeled on English law but does not follow recent English Law statutory enactments, and differs from laws applicable to United States corporations and their shareholders. Set forth below is a summary of some significant differences between the provisions of the Companies Law applicable to us and, for comparison purposes, the laws applicable to companies incorporated in the State of Delaware and their shareholders.

### Mergers and similar arrangements

The Companies Law allows for the merger of two or more companies into either one consolidated company or one or more company(ies) merged into another so as to form a single surviving company. The merger or consolidation of two or more companies under Cayman Islands law requires the directors of the companies to enter into and to approve a written plan of merger or consolidation, which must also be authorized by a special resolution of each constituent company, in which regard see "— Ordinary Shares — Voting Rights" above, and such other authorization, if any, as may be specified in such companies' articles of association. In relation to any merger or consolidation under the Companies Law, dissenting shareholders have certain limited appraisal rights in circumstances which are similar to those available to dissenting shareholders of a Delaware corporation, providing rights to receive payment in cash for the judicially determined fair value of the shares. Appraisal rights are ordinarily available where the consideration offered under the merger is payable in cash or, in some instances, the unlisted securities of a third party.

The Companies Law also includes statutory provisions that facilitate the reconstruction and amalgamation of companies, provided that such a scheme of arrangement is approved by shareholders or creditors who represent a majority in number and 75% in value of each such class of shareholders or creditors who attend and vote, either in person or by proxy, at a meeting or meetings convened for that purpose. The convening of meetings to consider any such scheme of arrangement, and the implementation of the scheme, must be sanctioned by the Grand Court of the Cayman Islands. While a dissenting shareholder has the right to express to the court the view that the transaction ought not to be approved, the court can be expected to approve the arrangement if it determines that:

- the statutory provisions as to the dual majority vote have been met;
- · the shareholders have been fairly represented at the meeting in question and the classes properly delineated;
- the arrangement is such that a businessman would reasonably approve; and
- · the arrangement is not one that would more properly be sanctioned under some other provision of the Companies Law.

If a scheme of arrangement is thus approved, the dissenting shareholders would have no rights comparable to appraisal rights, which would otherwise ordinarily be available to dissenting shareholders of a Delaware corporation.

When a tender offer to acquire shares is made and accepted (within four months) by holders of not less than 90% of the shares subject to such offer, the offeror may, within a two-month period following the expiration of the initial four month period, require the holders of the remaining shares to transfer such shares on the terms of the offer. An objection can be made to the Grand Court of the Cayman Islands but this is unlikely to succeed unless there is evidence of fraud, bad faith, collusion or inequitable treatment of shareholders.

### Shareholders' suits

We are not aware of any reported class action having been brought in a Cayman Islands court. Derivative actions have been brought in the Cayman Islands courts, and the Cayman Islands courts have confirmed the availability for such actions. In principle, we will normally be the proper plaintiff and a derivative action may not be brought by a shareholder. However, based on English authorities, which would in all likelihood be of persuasive authority in the Cayman Islands, there are exceptions to the foregoing principle, including when:

- a company acts or proposes to act illegally or ultra vires (beyond the scope of its authority);
- the act complained of, although not ultra vires, could be effected if duly authorized by a special resolution that has not been obtained;
   and

those who control the company are perpetrating a "fraud on the minority."

### Fiduciary duties of directors

Under Delaware corporate law, a director of a Delaware corporation has a fiduciary duty to the corporation and its shareholders. This duty has two components, the duty of care and the duty of loyalty. The duty of care requires that a director act in good faith, with the care that an ordinarily prudent person would exercise under similar circumstances. Under this duty, a director must inform himself of, and disclose to shareholders, all material information reasonably available regarding a significant transaction. The duty of loyalty requires that a director must act in a manner he or she reasonably believes to be in the best interests of the corporation. A director must not use his or her corporate position for personal gain or advantage. This duty prohibits self-dealing by a director and mandates that the best interests of the corporation and its shareholders take precedence over any interest possessed by a director, officer or controlling shareholder and not shared by the shareholders generally. In general, actions of a director are presumed to have been made on an informed basis, in good faith and in the honest belief that the action taken was in the best interests of the corporation. However, this presumption may be rebutted by evidence of a breach of one of the fiduciary duties. Should such evidence be presented concerning a transaction by a director, the director must prove the procedural fairness of the transaction and that the transaction was of fair value to the corporation.

As a matter of Cayman Islands law, a director of a Cayman Islands company is in the position of a fiduciary with respect to the company and therefore it is considered that he owes the following duties to the company: a duty to act in good faith and in what he considers to be in the best interests of the company; a duty not to make a profit out of his position as director (unless the company permits him to do so); a duty to exercise his powers for the purposes for which they are conferred; and a duty not to put himself in a position where the interests of the company conflict with his personal interest or his duty to a third party. A director of a Cayman Islands company owes to the company a duty to act with skill and care. A director will need to exhibit in the performance of his duties both the degree of skill than may reasonably be expected from a subjective perspective determined by reference to his knowledge and experience and the skill and care objectively to be expected from a person occupying office as a director of the company.

Under our amended and restated memorandum and articles of association, directors who are in any way, whether directly or indirectly, interested in a contract or proposed contract with our company must declare the nature of their interest at a meeting of the board of directors. Following such declaration, a director may vote in respect of any contract or proposed contract notwithstanding his interest; provided that, in exercising any such vote, such director's duties remain as described above.

### Written consent of shareholders

Under Delaware corporate law, unless otherwise provided in the certificate of incorporation, any action to be taken at any annual or special meeting of shareholders of a corporation may be taken by written consent of the holders of outstanding stock having not less than the minimum number of votes that would be necessary to take that action at a meeting at which all shareholders entitled to vote were present and voted. In addition, a corporation may eliminate the right of shareholders to act by written consent through amendment to its certificate of incorporation.

Cayman Islands law and our amended and restated memorandum and articles of association provide that shareholders may adopt an ordinary resolution or a special resolution by way of unanimous written resolution signed by or on behalf of each shareholder who would have been entitled to vote on such matter at a general meeting without a meeting being held.

## Shareholder proposals

Under Delaware corporate law, a shareholder has the right to put any proposal before the shareholders at the annual meeting, provided that such shareholder complies with the notice provisions in the governing

documents. A special meeting may be called by the board of directors or any other person authorized to do so in the governing documents, but shareholders may be precluded from calling special meetings.

Under the laws of the Cayman Islands, a shareholder can only put a proposal before the shareholders at any general meeting in respect of any matter requiring a special resolution if it is set out in the notice calling the meeting. There is no right to introduce new business in respect of any matter requiring a special resolution at any meeting. A general meeting may be called by the board of directors or any other person authorized to do so in the articles of association, but shareholders may be precluded from calling general meetings. Under our amended and restated memorandum and articles of association general meetings shall also be convened on the requisition in writing of any shareholder or shareholders entitled to attend and vote at general meetings of the company and to exercise at least a majority of the voting power permitted to be exercised at any such meeting, deposited at the office specifying the objects of the meeting for a date no later than 21 days from the date of deposit of the requisition signed by such shareholders, and if the directors do not convene such meeting for a date not later than 45 days after the date of such deposit, such shareholders themselves may convene the general meeting in the same manner, as nearly as possible, as that in which general meetings may be convened by the directors, and all reasonable expenses incurred by such shareholders as a result of the failure of the directors to convene the general meeting shall be reimbursed to them by the company. As an exempted Cayman Islands company, we are not obliged by law to call shareholders' annual general meetings.

Under Delaware corporate law, a corporation is required to set a minimum quorum of one-third of the issued and outstanding shares for a shareholders meeting. Cayman Islands law permits a company's articles to have any quorum. See "— Ordinary Shares — Voting Rights."

### Cumulative voting

Under Delaware corporate law, cumulative voting for elections of directors is not permitted unless the corporation's certificate of incorporation specifically provides for it. Cumulative voting potentially facilitates the representation of minority shareholders on a board of directors since it permits a minority shareholder to cast all the votes to which such shareholder is entitled on a single director, which increases such shareholder's voting power with respect to electing such director.

There are no prohibitions in relation to cumulative voting under the laws of the Cayman Islands, but our amended and restated memorandum and articles of association do not provide for cumulative voting. As a result, our shareholders are not afforded any less protection or fewer rights on this issue than shareholders of a Delaware corporation.

### Election and removal of directors

Under Delaware corporate law, unless otherwise specified in the certificate of incorporation or bylaws of a corporation, directors are elected by a plurality of the votes of the shares entitled to vote on the election of directors and may be removed with or without cause (or, with respect to a classified board, only with cause unless the certificate of incorporation provides otherwise) by the approval of a majority of the outstanding shares entitled to vote.

Similarly, as permitted by the Companies Law and pursuant to our amended and restated memorandum and articles of association, our board of directors will be divided into three classes with staggered, three-year terms. At each annual meeting of shareholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election. The election of directors shall be by a plurality of the votes of the shares entitled to vote on the election of directors.

In addition, subject to the maximum number of directors designated by resolution of the board of directors, additional directors may be appointed from time to time by the board of Directors or by ordinary resolution either as a result of a casual vacancy or as an additional director.

Directors may be removed or replaced by an ordinary resolution of the shareholders.

### Written consent of directors

Under Delaware corporate law, a written consent of the directors must be unanimous to take effect. The position under our amended and restated memorandum and articles of association is the same in this regard.

### Indemnification of directors and executive officers and limitation of liability

Cayman Islands law does not limit the extent to which a company's amended and restated memorandum and articles of association may provide for indemnification of officers and directors, except to the extent any such provision may be held by the Cayman Islands courts to be contrary to public policy, such as to provide indemnification against civil fraud or the consequences of committing a crime. Our amended and restated memorandum and articles of association, which will become effective upon the completion of this offering, provide that our board of directors and officers shall be indemnified from and against all liability which they incur in execution of their duty in their respective offices, except liability incurred by reason of such directors' or officers' dishonesty, willful default or fraud. This standard of conduct is generally the same as permitted under Delaware corporate law.

### Enforcement of civil liabilities

The Cayman Islands has a less developed body of securities laws as compared to the United States and provides less protection to investors. Additionally, Cayman Islands companies may not have standing to sue before the Federal courts of the United States. Although there is no statutory enforcement in the Cayman Islands of judgments obtained in the United States, the courts of the Cayman Islands will recognize a foreign judgment as the basis for a claim at common law in the Cayman Islands provided such judgment:

- is one in respect of which the foreign court had jurisdiction over the defendant according to Cayman Islands conflict of law rules;
- is final and conclusive;
- is either for a liquidated sum not in respect of penalties or taxes or a fine or similar fiscal or revenue obligations or, in certain circumstances, for *in personam* non-money relief; and
- was neither obtained in a manner, nor is of a kind enforcement of which is contrary to natural justice or the public policy of the Cayman Islands.

As a result of English case law, which will likely be highly persuasive in the Cayman Islands, the Cayman Islands Courts may also have discretion to enforce judgments obtained in foreign bankruptcy proceedings in other circumstances.

### Anti-money laundering — Cayman Islands

In order to comply with legislation or regulations aimed at the prevention of money laundering, we are required to adopt and maintain anti-money laundering procedures, and may require subscribers to provide evidence to verify their identity and source of funds. Where permitted, and subject to certain conditions, we may also delegate the maintenance of our anti-money laundering procedures (including the acquisition of due diligence information) to a suitable person.

We reserve the right to request such information as is necessary to verify the identity of a subscriber. In the event of delay or failure on the part of the subscriber in producing any information required for verification purposes, we may refuse to accept the application, in which case any funds received will be returned without interest to the account from which they were originally debited.

We also reserve the right to refuse to make any distribution payment to a shareholder if our directors or officers suspect or are advised that the payment of such distribution to such shareholder might result in a breach of applicable anti-money laundering or other laws or regulations by any person in any relevant jurisdiction, or if such refusal is considered necessary or appropriate to ensure our compliance with any such laws or regulations in any applicable jurisdiction.

If any person resident in the Cayman Islands knows or suspects or has reason for knowing or suspecting that another person is engaged in criminal conduct or is involved with terrorism or terrorist property and the information for that knowledge or suspicion came to their attention in the course of their business in the regulated sector, or other trade, profession, business or employment, the person will be required to report such knowledge or suspicion to (i) the Financial Reporting Authority of the Cayman Islands, pursuant to the Proceeds of Crime Law (2018 Revision) if the disclosure relates to criminal conduct or (ii) to a police officer of the rank of constable or higher, or the Financial Reporting Authority, pursuant to the Terrorism Law (2018 Revision) if the disclosure relates to involvement with terrorism or terrorist financing and property. Such a report shall not be treated as a breach of confidence or of any restriction upon the disclosure of information imposed by any enactment or otherwise.

### Variation of rights of shares

Under Delaware corporate law, a corporation may vary the rights of a class of shares with the approval of a majority of the outstanding shares of such class, unless the certificate of incorporation provides otherwise.

Under Cayman Islands law and our amended and restated memorandum and articles of association, if our share capital is divided into more than one class of shares, we may vary the rights attached to any class with the sanction of a resolution passed by not less than two-thirds of the votes attaching to the shares of the relevant class cast in a meeting of the holders of the shares of that class, or by the written consent of the holders of not less than two-thirds of the shares of that class.

#### Sale of assets

Under Delaware corporate law, a vote of the shareholders is required to approve a sale of assets only when all or substantially all assets are being sold to a person other than a subsidiary of the company.

The Companies Law contains no specific restrictions on the powers of directors to dispose of assets of a company. As a matter of general law, in the exercise of those powers, the directors must discharge their duties of care and to act in good faith, for a proper purpose and in the interests of the company.

#### Transactions with interested shareholders

The Delaware General Corporation Law contains a business combination statute applicable to Delaware corporations whereby, unless the corporation has specifically elected not to be governed by such statute by amendment to its certificate of incorporation, it is prohibited from engaging in certain business combinations with an "interested shareholder" for three years following the date that such person becomes an interested shareholder. An interested shareholder generally is a person or a group who or which owns or owned 15% or more of the target's outstanding voting stock within the past three years.

This has the effect of limiting the ability of a potential acquirer to make a two-tiered bid for the target in which all shareholders would not be treated equally. The statute does not apply if, among other things, prior to the date on which such shareholder becomes an interested shareholder, the board of directors approves either the business combination or the transaction which resulted in the person becoming an interested shareholder. This encourages any potential acquirer of a Delaware corporation to negotiate the terms of any acquisition transaction with the target's board of directors.

Cayman Islands law has no comparable statute. As a result, we cannot avail ourselves of the types of protections afforded by the Delaware business combination statute. However, although Cayman Islands law does not regulate transactions between a company and its significant shareholders, it does provide that such transactions must be entered into bona fide in the best interests of the company and not with the effect of constituting a fraud on the minority shareholders.

### Rights of non-resident or foreign shareholders

There are no limitations imposed by our amended and restated memorandum and articles of association on the rights of non-resident or foreign shareholders to hold or exercise voting rights on our shares. As similarly provided under Delaware corporate law, there are no restrictions on foreign or non-resident ownership or management of a Cayman Islands exempted company under Cayman Islands law. In addition, there are no provisions in our amended and restated memorandum and articles of association governing the ownership threshold above which shareholder ownership must be disclosed.

### Dissolution and winding up

Under the Delaware General Corporation Law, unless the board of directors approves the proposal to dissolve, dissolution must be approved by shareholders holding 100% of the total voting power of the corporation. Only if the dissolution is initiated by the board of directors may it be approved by a simple majority of the corporation's outstanding shares. Delaware law allows a Delaware corporation to include in its certificate of incorporation a supermajority voting requirement in connection with a dissolution initiated by the board of directors. Under the Companies Law of the Cayman Islands and our amended and restated memorandum and articles of association, our company may be voluntarily dissolved, liquidated or wound up only by a special resolution of our shareholders, in which regard see "— Ordinary Shares — Voting Rights" above. In addition, a company may be wound up by the Grand Court of the Cayman Islands if the company is unable to pay its debts or if the court is of the opinion that it is just and equitable that our company is wound up.

### Inspection of books and records

Under Delaware corporate law, any shareholder of a corporation may for any proper purpose inspect or make copies of the corporation's stock ledger, list of shareholders and other books and records.

Our shareholders will have no general right under Cayman Islands law to inspect or obtain copies of our list of shareholders or corporate records except our memorandum and restated articles of association.

#### Amendment of governing documents

Under Delaware corporate law, a corporation's certificate of incorporation may be amended only if adopted and declared advisable by the board of directors and approved by a majority of the outstanding shares entitled to vote, and the bylaws may be amended with the approval of a majority of the outstanding shares entitled to vote and may, if so provided in the certificate of incorporation, also be amended by the board of directors. As permitted by Cayman Islands law, our amended and restated memorandum and articles of association may be amended with the sanction of a special resolution of shareholders.

### **Transfer Agent and Registrar**

The transfer agent and registrar for our ordinary shares will be Computershare Trust Company, N.A.

### **Stock Exchange Listing**

We applied to have our ordinary shares listed on the Nasdaq Global Select Market under the symbol "MGTX."

#### SHARES ELIGIBLE FOR FUTURE SALE

Immediately prior to this offering, there was no public market for our ordinary shares. Future sales of substantial amounts of ordinary shares in the public market, or the perception that such sales may occur, could adversely affect the market price of our ordinary shares.

Upon the closing of this offering, we will have outstanding an aggregate of 27,184,140 ordinary shares, assuming the issuance of 5,000,000 ordinary shares offered by us in this offering (or 27,934,140 ordinary shares if the underwriters exercise their option to purchase 750,000 additional shares in full), and no exercise of options after April 30, 2018. Of these shares, all shares sold in this offering will be freely tradable without restriction or further registration under the Securities Act, except for any shares purchased by our "affiliates," as that term is defined in Rule 144 under the Securities Act, whose sales would be subject to the Rule 144 resale restrictions described below, other than the holding period requirement.

The remaining 22,184,140 ordinary shares will be "restricted securities," as that term is defined in Rule 144 under the Securities Act. These restricted securities are eligible for public sale only if they are registered under the Securities Act or if they qualify for an exemption from registration under Rules 144 or 701 under the Securities Act, which are summarized below. We expect that substantially all of these shares will be subject to the 180-day lock-up period under the lock-up agreements described below. Upon expiration of the lock-up period, we estimate that approximately 22,184,140 shares will be available for sale in the public market, subject in some cases to applicable volume limitations under Rule 144.

In addition, of the 1,614,403 ordinary shares that were subject to share options outstanding as of April 30, 2018, options to purchase 249,158 ordinary shares were vested as of April 30, 2018 and, upon exercise, these shares will be eligible for sale subject to the lock—up agreements described below and Rules 144 and 701 under the Securities Act.

### **Lock-up Agreements**

We and each of our directors and executive officers and holders of substantially all of our outstanding ordinary shares have agreed that, without the prior written consent of Merrill Lynch, Pierce, Fenner & Smith Incorporated and Barclays Capital Inc., we and they will not, subject to certain exceptions, during the period ending 180 days after the date of this prospectus, offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any ordinary shares or any securities convertible into or exercisable or exchangeable for ordinary shares; or enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of our ordinary shares, whether any transaction described above is to be settled by delivery of our ordinary shares or such other securities, in cash or otherwise.

Upon the expiration of the lock-up period, substantially all of the shares subject to such lock-up restrictions will become eligible for sale, subject to the limitations discussed above. For a further description of these lock-up agreements, please see "Underwriting."

## **Rule 144**

## **Affiliate Resales of Restricted Securities**

In general, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is an affiliate of ours, or who was an affiliate at any time during the 90 days before a sale, who has beneficially owned ordinary shares for at least six months would be entitled to sell in

"broker's transactions" or certain "riskless principal transactions" or to market makers, a number of shares within any three-month period that does not exceed the greater of:

- 1% of the number of ordinary shares then outstanding, which will equal approximately shares immediately after the closing of this offering based on the number of ordinary shares outstanding as of April 30, 2018; or
- the average weekly trading volume in our ordinary shares on the Nasdaq Global Select Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Such sales by affiliates must also comply with the manner of sale, current public information and notice provisions of Rule 144.

Certain of our existing shareholders and their affiliated entities have indicated an interest in purchasing an aggregate of up to approximately \$40.0 million of our ordinary shares in this offering at the initial public offering price per share. Any such shares purchased by shareholders who are considered to be our affiliates cannot be resold in the public market immediately following this offering as a result of restrictions under securities laws, but will be able to be sold following the expiration of these restrictions, as described above However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could determine to sell more, fewer or no shares to any of these potential purchasers, and any of these potential purchasers could determine to purchase more, fewer or no shares in this offering.

### Non-Affiliate Resales of Restricted Securities

In general, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is not an affiliate of ours at the time of sale, and has not been an affiliate at any time during the 90 days preceding a sale, and who has beneficially owned ordinary shares for at least six months but less than a year, is entitled to sell such shares subject only to the availability of current public information about us. If such person has held our shares for at least one year, such person can resell under Rule 144(b)(1) without regard to any Rule 144 restrictions, including the 90-day public company requirement and the current public information requirement.

Non-affiliate resales are not subject to the manner of sale, volume limitation or notice filing provisions of Rule 144.

### **Rule 701**

In general, under Rule 701, any of an issuer's employees, directors, officers, consultants or advisors who purchases shares from the issuer in connection with a compensatory stock or option plan, or other written agreements, before the effective date of a registration statement under the Securities Act is entitled to sell such shares 90 days after such effective date in reliance on Rule 144. An affiliate of the issuer can resell shares in reliance on Rule 144 without having to comply with the holding period requirement, and non-affiliates of the issuer can resell shares in reliance on Rule 144 without having to comply with the current public information and holding period requirements.

The Securities and Exchange Commission has indicated that Rule 701 will apply to typical stock options granted by an issuer before it becomes subject to the reporting requirements of the Exchange Act, along with the shares acquired upon exercise of such options, including exercises after an issuer becomes subject to the reporting requirements of the Exchange Act.

## **Equity Plans**

We intend to file one or more registration statements on Form S-8 under the Securities Act to register all ordinary shares subject to outstanding stock options and ordinary shares issued or issuable under our stock plans. We expect to file the registration statement covering shares offered pursuant to our stock plans shortly after the date of this prospectus, permitting the resale of such shares by non-affiliates in the public market without restriction under the Securities Act and the sale by affiliates in the public market, subject to compliance with the resale provisions of Rule 144.

### **CERTAIN CAYMAN ISLANDS TAX CONSIDERATIONS**

The following discussion is a summary of the material Cayman Islands tax considerations relating to the purchase, ownership and disposition of our ordinary shares. There is, at present, no direct taxation in the Cayman Islands and interest, dividends and gains payable to the company will be received free of all Cayman Islands taxes. The company has received an undertaking from the Government of the Cayman Islands to the effect that, for a period of twenty years from the date of the undertaking, no law that thereafter is enacted in the Cayman Islands imposing any tax or duty to be levied on profits, income or on gains or appreciation, or any tax in the nature of estate duty or inheritance tax, will apply to any property comprised in or any income arising under the company, or to the shareholders thereof, in respect of any such property or income.

No stamp duty in the Cayman Islands is payable in respect of the issue of any ordinary shares or an instrument of transfer in respect of an ordinary share.

#### CERTAIN UNITED KINGDOM TAX CONSIDERATIONS

The following statements are of a general nature and do not purport to be a complete analysis of all potential UK tax consequences of acquiring, holding and disposing of our ordinary shares. They are based on current UK tax law and on the current published practice of Her Majesty's Revenue and Customs ("HMRC") (which may not be binding on HMRC), as of the date of this prospectus, all of which are subject to change, possibly with retrospective effect. They are intended to address only certain United Kingdom tax consequences for holders of our ordinary shares who are tax resident in (and only in) the United Kingdom, and in the case of individuals, domiciled in (and only in) the United Kingdom (except where expressly stated otherwise) who are the absolute beneficial owners of our ordinary shares and any dividends paid on them and who hold our ordinary shares as investments (other than in an individual savings account or a self-invested personal pension). They do not address the UK tax consequences which may be relevant to certain classes of holders of our ordinary shares such as traders, brokers, dealers, banks, financial institutions, insurance companies, investment companies, collective investment schemes, tax-exempt organizations, trustees, persons connected with us or a member of our group, persons holding our ordinary shares as part of hedging or conversion transactions, holders of our ordinary shares who have (or are deemed to have) acquired our ordinary shares by virtue of an office or employment, and holders of our ordinary shares who either directly or indirectly holds or controls 10% or more of the our share capital (or class thereof), voting power or profits.

The following is intended only as a general guide and is not intended to be, nor should it be considered to be, legal or tax advice to any particular prospective subscriber for, or purchaser of, our ordinary shares. Accordingly, prospective subscribers for, or purchasers of, our ordinary shares who are in any doubt as to their tax position regarding the acquisition, ownership and disposition of our ordinary shares or who are subject to tax in a jurisdiction other than the United Kingdom should consult their own tax advisers.

### The Company

It is the intention of the directors to conduct the affairs of the Company so that the central management and control of the Company is exercised in the UK. As a result, the Company is expected to be treated as resident in the UK for UK tax purposes. Accordingly we expect to be subject to UK taxation on our income and gains, except where an exemption applies.

We may be treated as a dual resident company for UK tax purposes. As a result, our right to claim certain reliefs from UK tax may be restricted, and changes in law or practice in the United Kingdom could result in the imposition of further restrictions on our right to claim UK tax reliefs.

#### Taxation of dividends

#### Withholding tax

We will not be required to withhold UK tax at source when paying dividends on our ordinary shares.

### Income tax

An individual holder of our ordinary shares who is resident for tax purposes in the UK may, depending on his or her particular circumstances, be subject to UK tax on dividends received from us. Dividend income is treated as the top slice of the total income chargeable to UK income tax. An individual holder of our ordinary shares who is not resident for tax purposes in the UK should not be chargeable to UK income tax on dividends received from us unless he or she carries on (whether solely or in partnership) any trade, profession or vocation in the UK through a permanent establishment to which our ordinary shares are attributable. There are certain exceptions for trading in the UK through independent agents, such as some brokers and investment managers.

All dividends received by a UK resident individual holder of our ordinary shares from us or from other sources will form part of that holder's total income for income tax purposes and will constitute the top slice of that income. A nil rate of income tax will apply to the first £2,000 of taxable dividend income received by the holder of our ordinary shares in a tax year. Income within the nil rate band will be taken into account in determining whether income in excess of the nil rate band falls within the basic rate, higher rate or additional rate tax bands. Where the dividend income is above the £2,000 dividend allowance, the first £2,000 of the dividend income will be charged at the nil rate and any excess amount will be taxed at 7.5 per cent. to the extent that the excess amount falls within the basic rate tax band, 32.5 per cent. to the extent that the excess amount falls within the higher rate tax band and 38.1 per cent. to the extent that the excess amount falls within the additional rate tax band.

### Corporation tax

Corporate holders of our ordinary shares which are resident for tax purposes in the UK should not be subject to UK corporation tax on any dividend received from us so long as the dividends qualify for exemption (as is likely) and certain conditions are met (including anti-avoidance conditions). Corporate holders of our ordinary shares which are not resident in the United Kingdom will not generally be subject to UK corporation tax on dividends unless they are carrying on a trade, profession or vocation in the United Kingdom through a permanent establishment in connection with which such shares are attributable.

A holder of our ordinary shares who is resident outside the United Kingdom may be subject to non-UK taxation on dividend income under local law.

### Taxation of capital gains

### UK resident holders of our ordinary shares

A disposal or deemed disposal of our ordinary shares by an individual or corporate holder of such shares who is tax resident in the United Kingdom may, depending on that holder's circumstances and subject to any available exemptions or reliefs, give rise to a chargeable gain or allowable loss for the purposes of UK taxation of chargeable gains.

Any chargeable gain (or allowable loss) will generally be calculated by reference to the consideration received for the disposal of our ordinary shares less the allowable cost to the holder of acquiring such shares.

The applicable tax rates for individual holders of our ordinary shares realizing a gain on the disposal of such shares is, broadly, 10% for basic rate taxpayers and 20% for higher and additional rate taxpayers. The applicable tax rates for corporate holders of our ordinary shares realizing a gain on the disposal of such shares is currently 19%.

### Non-UK holders of our ordinary shares

Holders of our ordinary shares who are not resident in the United Kingdom and, in the case of an individual holder of our ordinary shares, not temporarily non-resident, should not be liable for UK tax on capital gains realized on a sale or other disposal of our ordinary shares unless such shares are attributable to a trade, profession or vocation carried on in the United Kingdom through a branch or agency or, in the case of a corporate holder of our ordinary shares, through a permanent establishment. Holders of our ordinary shares who are not resident in the United Kingdom may be subject to non-UK taxation on any gain under local law.

Generally, an individual holder of our ordinary shares who has ceased to be resident in the United Kingdom for tax purposes for a period of five years or less and who disposes of our ordinary shares during that period may be liable on their return to the United Kingdom to UK taxation on any capital gain realized (subject to any available exemption or relief).

#### UK stamp duty ("Stamp Duty") and UK stamp duty reserve tax ("SDRT")

The statements below are intended as a general guide to the current position relating to Stamp Duty and SDRT and apply to any holders of our ordinary shares irrespective of their place of tax residence.

No UK Stamp Duty or SDRT, will be payable on the issue of ordinary shares, subject to the comments below.

Stamp Duty will in principle be payable on any instrument of transfer of ordinary shares that is executed in the United Kingdom or that relates to any property situated, or to any matter or thing done or to be done, in the United Kingdom. An exemption from Stamp Duty is available on an instrument transferring ordinary shares where the amount or value of the consideration is £1,000 or less and it is certified on the instrument that the transaction effected by the instrument does not form part of a larger transaction or series of transactions in respect of which the aggregate amount or value of the consideration exceeds £1,000. Holders of ordinary shares should be aware that, even where an instrument of transfer is in principle subject to Stamp Duty, Stamp Duty is not required to be paid unless it is necessary to rely on the instrument for legal purposes, for example to register a change of ownership or in litigation in a UK court.

Provided that ordinary shares are not registered in any register maintained in the United Kingdom by or on behalf of us and are not paired with any shares issued by a UK incorporated company, any agreement to transfer ordinary shares will not be subject to SDRT. The ordinary shares are not paired with any shares issued by a UK incorporated company and we currently do not intend that any register of ordinary shares will be maintained in the United Kingdom.

If ordinary shares were to be registered in a register maintained in the United Kingdom by or on behalf of us or paired with any shares issued by a UK incorporated company then, subject to the comments below, where ordinary shares are transferred or issued to, or to a nominee or agent for, a person whose business is or includes the provision of clearance services or issuing depositary receipts (but not including CREST), SDRT may be payable at a rate of 1.5% of the amount or value of the consideration payable for (or, in certain circumstances, the value of) the ordinary shares. This liability for SDRT will be payable by the clearance service or depositary receipt operator or its nominee, as the case may be, but in practice participants in the clearance service or depositary receipt scheme will generally be required to reimburse them for such cost. It is understood that H.M. Revenue and Customs regards the facilities of DTC as a clearance service for these purposes.

Following litigation, H.M. Revenue and Customs has confirmed that it will no longer seek to apply the above 1.5% SDRT charge (or a corresponding Stamp Duty charge) on the issue of shares into a clearance service or depositary receipt system established in a European Member State on the basis that the charge is not compatible with EU law. However, their view is that the 1.5% charge will still apply to the transfer of shares into such a clearance service or depositary receipts system where the transfer is not an integral part of the issue of share capital. There is an exception from the 1.5% charge on the transfer to, or to a nominee or agent for, a clearance service where the clearance service has made and maintained an election under section 97A(1) of the UK Finance Act 1986 which has been approved by HMRC. We are not aware of any section 97A election having been made by DTC. Accordingly, holders of ordinary shares should consult their own independent professional advisers before incurring or reimbursing the costs of such a 1.5% SDRT charge.

# MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES

The following discussion describes the material U.S. federal income tax consequences to U.S. Holders (as defined below) under present law of an investment in our ordinary shares. It is not a comprehensive description of all tax considerations that may be relevant to a particular person's decision to acquire the ordinary shares. The effects of any applicable state or local laws, other U.S. federal tax laws such as estate and gift tax laws, the alternative minimum tax or the Medicare contribution tax on net investment income, are not discussed. This summary applies only to investors who acquire the ordinary shares in exchange for cash, hold the ordinary shares as capital assets (generally, property held for investment) and who have the U.S. dollar as their functional currency. This discussion is based on the U.S. Internal Revenue Code of 1986, as amended, or the Code, U.S. Treasury regulations promulgated thereunder, judicial decisions, published rulings and administrative pronouncements of the U.S. Internal Revenue Service, or the IRS, all as in effect as of the date of this prospectus. All of the foregoing authorities are subject to change, which change could apply retroactively and could alter the tax consequences described below.

The following discussion does not address all U.S. federal income tax consequences relevant to a holder's particular circumstances or to holders subject to particular rules, including:

- U.S. expatriates and certain former citizens or long-term residents of the United States;
- persons whose functional currency is not the U.S. dollar;
- persons holding ordinary shares as part of a hedge, straddle or other risk reduction strategy or as part of a conversion transaction or other integrated investment;
- banks, insurance companies, and other financial institutions;
- real estate investment trusts or regulated investment companies;
- brokers, dealers or traders in securities, commodities or currencies;
- S corporations or entities or arrangements treated as partnerships for U.S. federal income tax purposes;
- · tax-exempt organizations or governmental organizations;
- individual retirement accounts or other tax deferred accounts;
- persons who acquired the ordinary shares pursuant to the exercise of any employee share option or otherwise as compensation;
- persons that own or are deemed to own 10% or more of our stock by vote or value;
- persons subject to special tax accounting rules as a result of any item of gross income with respect to the ordinary shares being taken into account in an applicable financial statement;
- · persons that hold ordinary shares through a permanent establishment or fixed base outside the United States; and
- persons deemed to sell ordinary shares under the constructive sale provisions of the Code.

U.S. HOLDERS ARE URGED TO CONSULT THEIR TAX ADVISORS REGARDING THE APPLICATION OF THE U.S. FEDERAL TAX RULES TO THEIR PARTICULAR CIRCUMSTANCES AS WELL AS THE U.S. STATE, LOCAL AND NON-U.S. TAX CONSEQUENCES TO THEM OF THE PURCHASE, OWNERSHIP AND DISPOSITION OF ORDINARY SHARES.

For purposes of this discussion, a "U.S. Holder" is a beneficial owner of ordinary shares that, for U.S. federal income tax purposes, is or is treated as any of the following:

• an individual who is a citizen or resident of the United States;

- a corporation (or another entity taxable as a corporation) created or organized under the laws of the United States, any state thereof, or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust that (1) is subject to the supervision of a U.S. court and the control of one or more "United States persons" (within the meaning of Section 7701(a)(30) of the Code), or (2) has a valid election in effect to be treated as a United States person for U.S. federal income tax purposes.

If you are a partner in an entity taxable as a partnership for U.S. federal income tax purposes that holds ordinary shares, your tax treatment generally will depend on your status and the activities of the partnership. Partnerships holding ordinary shares and the partners in such partnerships should consult their tax advisors regarding the U.S. federal income tax consequences applicable to them.

### Taxation of Dividends and Other Distributions on the Ordinary Shares

The discussion in this section "Taxation of Dividends and Other Distributions on the Ordinary Shares" is subject to the discussion regarding passive foreign investment companies below.

As discussed above under "Dividend Policy," the Company does not currently intend to declare dividends on the ordinary shares in the foreseeable future. In the event the Company does pay dividends, the gross amount of any distribution to you with respect to the ordinary shares will be included in your gross income as dividend income when actually or constructively received to the extent the distribution is paid out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles). To the extent the amount of the distribution exceeds our current and accumulated earnings and profits, it will be treated first as a return of your tax basis in the ordinary shares, and to the extent the amount of the distribution exceeds your tax basis, the excess will be taxed as capital gain. We do not intend to calculate our earnings and profits under U.S. federal income tax principles. Therefore, a U.S. Holder should expect that distributions will generally be reported as ordinary dividend income for such purposes. Dividends we pay will not be eligible for the dividends-received deduction available to corporations in respect of dividends received from U.S. corporations.

Subject to certain limitations, dividends paid by qualified foreign corporations to certain non-corporate U.S. Holders may be taxable at preferential tax rates. A non-U.S. corporation is generally treated as a qualified foreign corporation with respect to dividends paid on stock that is readily tradable on a securities market in the United States, such as the Nasdaq Global Select Market, on which the Company has applied to list the ordinary shares. However, the preferential tax rates discussed above will not apply if we are treated as a passive foreign investment company with respect to the U.S. Holder for the taxable year in which a dividend is paid or the preceding year. Non-corporate U.S. Holders should consult their tax advisers regarding the availability of the reduced tax rate on dividends. Dividends will be included in a U.S. Holder's income on the date of the U.S. Holder's receipt of the dividend.

Dividends will generally constitute foreign source income for foreign tax credit limitation purposes. Any tax withheld with respect to distributions on the ordinary shares may, subject to a number of complex limitations, be claimed as a foreign tax credit against such U.S. Holder's U.S. federal income tax liability or may be claimed as a deduction for U.S. federal income tax purposes. The limitation on foreign taxes eligible for credit is calculated separately with respect to specific classes of income. For this purpose, dividends distributed by us with respect to the ordinary shares generally will constitute "passive category income." The rules with respect to the foreign tax credit are complex and may depend upon a U.S. Holder's particular circumstances. You should consult your tax advisor regarding the availability of the foreign tax credit in light of your particular circumstances.

## **Taxation of Disposition of the Ordinary Shares**

The discussion in this section "Taxation of Disposition of the Ordinary Shares" is subject to the discussion regarding passive foreign investment companies below.

You will recognize gain or loss on any sale, exchange or other taxable disposition of ordinary shares equal to the difference between the amount realized (in U.S. dollars) on the disposition and your tax basis (in U.S. dollars) in the ordinary shares. Any such gain or loss will be capital gain or loss, and will be long-term capital gain or loss if you have held the ordinary shares for more than one year at the time of the disposition. Otherwise, such gain or loss will be short-term capital gain or loss. Long-term capital gains recognized by certain non-corporate U.S. Holders, including individuals, generally will be taxable at reduced rates. The deductibility of capital losses is subject to limitations. Any such gain or loss you recognize generally will be treated as U.S. source income or loss for foreign tax credit limitation purposes. You should consult your tax advisor regarding the proper treatment of gain or loss in your particular circumstances.

### **Passive Foreign Investment Company**

Based on the current and anticipated value of our assets and the composition of our income, assets and operations, we do not believe we were a "passive foreign investment company," or PFIC, for the taxable year ending on December 31, 2017, and do not expect to be a PFIC for current taxable year. However, the application of the PFIC rules is subject to uncertainty in several respects, and we cannot assure you that the IRS will not take a contrary position. A non-U.S. corporation will be classified as a PFIC for any taxable year in which, after applying certain look-through rules, either:

- at least 75% of its gross income for such taxable year is passive income, or
- at least 50% of the value of its assets (based on an average of the quarterly values of the assets during a taxable year) is attributable to assets that produce or are held for the production of passive income.

For purposes of the above calculations, if a non-U.S. corporation owns, directly or indirectly, 25% or more of the total value of the outstanding shares of another corporation, it will be treated as if it (a) held a proportionate share of the assets of such other corporation and (b) received directly a proportionate share of the income of such other corporation. Passive income generally includes dividends, interest, rents, royalties and capital gains, but generally excludes rents and royalties which are derived in the active conduct of a trade or business and which are received from a person other than a related person.

A separate determination must be made each taxable year as to whether we are a PFIC (after the close of each such taxable year). Because the value of our assets for purposes of the asset test will generally be determined by reference to the market price of the ordinary shares, our PFIC status will depend in large part on the market price of the ordinary shares, which may fluctuate significantly. In addition, changes in the composition of our income or assets may cause us to become a PFIC.

If we are classified as a PFIC in any year with respect to which a U.S. Holder owns ordinary shares, we will continue to be treated as a PFIC with respect to such U.S. Holder in all succeeding years during which the U.S. Holder owns the ordinary shares, regardless of whether we continue to meet the tests described above unless we cease to be a PFIC and the U.S. Holder has made a "deemed sale" election under the PFIC rules.

If we are a PFIC for any taxable year during which you hold ordinary shares, you will be subject to special tax rules with respect to any "excess distribution" you receive and any gain you realize from a sale or other disposition (including a pledge) of ordinary shares. Distributions you receive in a taxable year that are greater than 125% of the average annual distributions you received during the shorter of the three preceding taxable years or your holding period for the ordinary shares will be treated as an excess distribution. Under these special tax rules, if you receive any excess distribution or realize any gain from a sale or other disposition of the ordinary shares:

the excess distribution or gain will be allocated ratably over your holding period for the ordinary shares,

- the amount allocated to the current taxable year, and any taxable year before the first taxable year in which we were a PFIC, will be treated as ordinary income, and
- the amount allocated to each other year will be subject to the highest tax rate in effect for that year and an interest charge generally applicable to underpayments of tax will be imposed on the resulting tax attributable to each such year.

The tax liability for amounts allocated to years before the year of disposition or "excess distribution" cannot be offset by any net operating losses for such years, and gains (but not losses) realized on the sale of ordinary shares cannot be treated as capital, even if you hold the ordinary shares as capital assets.

Certain elections may be available that would result in alternative treatments (such as mark-to-market treatment of the common shares). The adverse consequences of owning stock in a PFIC could be mitigated if a U.S. Holder makes a valid "qualified electing fund" election, or QEF election, which, among other things, would require a U.S. Holder to include currently in income its pro rata share of the PFIC's net capital gain and ordinary earnings, based on earnings and profits as determined for U.S. federal income tax purposes. We have not yet determined whether we would provide the information necessary for U.S. Holders of our ordinary shares to make qualified electing fund elections in the event we are or were classified as a PFIC.

If we are considered a PFIC, U.S. Holders will also be subject to annual information reporting requirements. If we are or become a PFIC, you should consult your tax advisor regarding any reporting requirements that may apply to you. U.S. Holders are urged to consult their tax advisors regarding the application of the PFIC rules to the ownership and disposition of the ordinary shares and the potential availability of a mark-to-market or QEF election.

#### **Information Reporting and Backup Withholding**

Dividend payments with respect to ordinary shares and proceeds from the sale, exchange or other disposition of ordinary shares may be subject to information reporting to the IRS and U.S. backup withholding. Certain U.S. Holders are exempt from backup withholding, including corporations and certain tax-exempt organizations. A U.S. Holder will be subject to backup withholding if such holder is not otherwise exempt and such holder:

- fails to furnish the holder's taxpayer identification number, which for an individual is ordinarily his or her social security number;
- furnishes an incorrect taxpayer identification number;
- is notified by the IRS that the holder previously failed to properly report payments of interest or dividends; or
- fails to certify under penalties of perjury that the holder has furnished a correct taxpayer identification number and that the IRS has not notified the holder that the holder is subject to backup withholding.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against the U.S. Holder's U.S. federal income tax liability, provided the required information is timely furnished to the IRS. U.S. Holders should consult their tax advisors regarding their qualification for an exemption from backup withholding and the procedures for obtaining such an exemption.

### **Additional Reporting Requirements**

Certain U.S. Holders who are individuals (and certain entities) that hold an interest in "specified foreign financial assets" (which may include the ordinary shares) are required to report information relating to such

assets, subject to certain exceptions (including an exception for ordinary shares held in accounts maintained by certain financial institutions). Penalties can apply if U.S. Holders fail to satisfy such reporting requirements. U.S. Holders should consult their tax advisors regarding the applicability of these requirements to their acquisition and ownership of ordinary shares.

#### UNDERWRITING

Merrill Lynch, Pierce, Fenner & Smith Incorporated and Barclays Capital Inc. are acting as representatives of each of the underwriters named below. Subject to the terms and conditions set forth in an underwriting agreement among us and the underwriters, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us, the number of ordinary shares set forth opposite its name below.

<u>Underwriter</u>	Number of Ordinary <u>Shares</u>
Merrill Lynch, Pierce, Fenner & Smith	
Incorporated	
Barclays Capital Inc.	
Evercore Group L.L.C.	
Chardan Capital Markets LLC	
Total	

Subject to the terms and conditions set forth in the underwriting agreement, the underwriters have agreed, severally and not jointly, to purchase all of the ordinary shares sold under the underwriting agreement if any of these ordinary shares are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the nondefaulting underwriters may be increased or the underwriting agreement may be terminated.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, or to contribute to payments the underwriters may be required to make in respect of those liabilities.

The underwriters are offering the ordinary shares, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel, including the validity of the ordinary shares, and other conditions contained in the underwriting agreement, such as the receipt by the underwriters of officer's certificates and legal opinions. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

Certain of our existing shareholders and their affiliated entities have indicated an interest in purchasing an aggregate of up to approximately \$40.0 million of our ordinary shares in this offering at the initial public offering price per share and on the same terms as the other purchasers in this offering. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could determine to sell more, fewer or no shares to any of these potential purchasers, and any of these potential purchasers could determine to purchase more, fewer or no shares in this offering. The underwriters will receive the same underwriting discount and commissions on these shares as they will on any other shares sold to the public in this offering.

### **Commissions and Discounts**

The representatives have advised us that the underwriters propose initially to offer the ordinary shares to the public at the public offering price set forth on the cover page of this prospectus and to dealers at that price less a concession not in excess of \$ per ordinary share. After the initial offering, the public offering price, concession or any other term of the offering may be changed. We have also agreed to reimburse the underwriters for an aggregate of up to \$50,000 for certain of their offering expenses, including counsel fees and expenses in connection with the clearance of this offering with the Financial Industry Regulatory Authority, or FINRA. In accordance with FINRA Rule 5110, these reimbursed expenses are deemed underwriting compensation for this offering.

The following table shows the public offering price, underwriting discount and proceeds before expenses to us. The information assumes either no exercise or full exercise by the underwriters of their option to purchase additional ordinary shares.

	Per Ordinary		
	Share	Without Option	With Option
Public offering price	\$	\$	\$
Underwriting discount	\$	\$	\$
Proceeds, before expenses, to us	\$	\$	\$
MeiraGTx Holdings plc			

The expenses of the offering, not including the underwriting discount, are estimated at \$2,750,000 and are payable by us.

#### **Option to Purchase Additional Ordinary Shares**

We have granted an option to the underwriters, exercisable for 30 days after the date of this prospectus, to purchase up to 750,000 additional ordinary shares at the public offering price, less the underwriting discount. If the underwriters exercise this option, each will be obligated, subject to conditions contained in the underwriting agreement, to purchase a number of additional ordinary shares proportionate to that underwriter's initial amount reflected in the above table.

#### **No Sales of Similar Securities**

We, our executive officers and directors and substantially all of our other existing security holders have agreed not to sell or transfer any ordinary shares or securities convertible into, exchangeable for, exercisable for, or repayable with ordinary shares, for 180 days after the date of this prospectus without first obtaining the written consent of Merrill Lynch, Pierce, Fenner & Smith Incorporated and Barclays Capital Inc. Specifically, we and these other persons have agreed, with certain limited exceptions, not to directly or indirectly:

- offer, pledge, sell or contract to sell any ordinary shares,
- sell any option or contract to purchase any ordinary shares,
- purchase any option or contract to sell any ordinary shares,
- grant any option, right or warrant for the sale of any ordinary shares,
- · lend or otherwise dispose of or transfer any ordinary shares,
- · request or demand that we file a registration statement related to the ordinary shares, or
- enter into any swap or other agreement that transfers, in whole or in part, the economic consequence of ownership of any ordinary shares whether any such swap or transaction is to be settled by delivery of shares or other securities, in cash or otherwise.

This lock-up provision applies to ordinary shares and to securities convertible into or exchangeable or exercisable for or repayable with ordinary shares. It also applies to ordinary shares owned now or acquired later by the person executing the agreement or for which the person executing the agreement later acquires the power of disposition.

## **Nasdaq Global Select Market Listing**

We expect the ordinary shares to be approved for listing on the Nasdaq Global Select Market, subject to notice of issuance, under the symbol "MGTX."

Before this offering, there has been no public market for our ordinary shares. The initial public offering price will be determined through negotiations between us and the representatives. In addition to prevailing market conditions, the factors to be considered in determining the initial public offering price will be:

- the valuation multiples of publicly traded companies that the representatives believe to be comparable to us,
- our financial information,
- the history of, and the prospects for, our company and the industry in which we compete,
- · an assessment of our management, its past and present operations, and the prospects for, and timing of, our future revenues,
- the present state of our development, and
- the above factors in relation to market values and various valuation measures of other companies engaged in activities similar to ours.

An active trading market for the ordinary shares may not develop. It is also possible that after the offering the ordinary shares will not trade in the public market at or above the initial public offering price.

The underwriters do not expect to sell more than 5% of the ordinary shares in the aggregate to accounts over which they exercise discretionary authority.

### Price Stabilization, Short Positions and Penalty Bids

Until the distribution of the ordinary shares is completed, SEC rules may limit underwriters and selling group members from bidding for and purchasing our ordinary shares. However, the representatives may engage in transactions that stabilize the price of the ordinary shares, such as bids or purchases to peg, fix or maintain that price.

In connection with the offering, the underwriters may purchase and sell our ordinary shares in the open market. These transactions may include short sales, purchases on the open market to cover positions created by short sales and stabilizing transactions. Short sales involve the sale by the underwriters of a greater number of ordinary shares than they are required to purchase in the offering. "Covered" short sales are sales made in an amount not greater than the underwriters' option to purchase additional ordinary shares described above. The underwriters may close out any covered short position by either exercising their option to purchase additional ordinary shares or purchasing ordinary shares in the open market. In determining the source of ordinary shares to close out the covered short position, the underwriters will consider, among other things, the price of ordinary shares available for purchase in the open market as compared to the price at which they may purchase ordinary shares through the option granted to them. "Naked" short sales are sales in excess of such option. The underwriters must close out any naked short position by purchasing ordinary shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of our ordinary shares in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of ordinary shares made by the underwriters in the open market prior to the completion of the offering.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representatives have repurchased ordinary shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

Similar to other purchase transactions, the underwriters' purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our ordinary shares or preventing or retarding a

decline in the market price of our ordinary shares. As a result, the price of our ordinary shares may be higher than the price that might otherwise exist in the open market. The underwriters may conduct these transactions on the Nasdaq Global Select Market, in the over-the-counter market or otherwise.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our ordinary shares. In addition, neither we nor any of the underwriters make any representation that the representatives will engage in these transactions or that these transactions, once commenced, will not be discontinued without notice.

#### **Electronic Distribution**

In connection with the offering, certain of the underwriters or securities dealers may distribute prospectuses by electronic means, such as e-mail.

#### Other Relationships

Some of the underwriters and their affiliates have engaged in, and may in the future engage in, investment banking and other commercial dealings in the ordinary course of business with us or our affiliates. They have received, or may in the future receive, customary fees and commissions for these transactions.

In addition, in the ordinary course of their business activities, the underwriters and their affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers. Such investments and securities activities may involve securities and/or instruments of ours or our affiliates. The underwriters and their affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or financial instruments and may hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments

#### **Notice to Prospective Investors in the European Economic Area**

In relation to each member state of the European Economic Area which has implemented the Prospectus Directive (each referred to as a "Member State"), no offer of ordinary shares which are the subject of the offering has been, or will be, made to the public in that Member State, other than under the following exemptions under the Prospectus Directive, if they have been implemented in that Member State:

- (a) to any legal entity which is a "qualified investor" as defined in the Prospectus Directive;
- (b) to fewer than 150 natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospective Directive, subject to obtaining the prior consent of the Underwriters for any such offer; or
- (c) in any other circumstances falling within Article 3(2) of the Prospectus Directive,

provided that no such offer of ordinary shares referred to in (a) to (c) above shall result in a requirement for the Company or any Underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Directive, or supplement a prospectus pursuant to Article 16 of the Prospectus Directive.

Each person located in a Member State to whom any offer of ordinary shares is made or who receives any communication in respect of an offer of ordinary shares, or who initially acquires any ordinary shares, will be deemed to have represented, warranted, acknowledged and agreed to and with each Underwriter and the Company that (1) it is a "qualified investor" within the meaning of the law in that Member State implementing Article 2(1)(e) of the Prospectus Directive; and (2) in the case of any ordinary shares acquired by it as a financial

intermediary as that term is used in Article 3(2) of the Prospectus Directive, the ordinary shares acquired by it in the offer have not been acquired on behalf of, nor have they been acquired with a view to their offer or resale to, persons in any Member State other than qualified investors, as that term is defined in the Prospectus Directive, or in circumstances in which the prior consent of the Underwriters has been given to the offer or resale; or where ordinary shares have been acquired by it on behalf of persons in any Member State other than qualified investors, the offer of those ordinary shares to it is not treated under the Prospectus Directive as having been made to such persons.

The Company, the Underwriters and their respective affiliates will rely upon the truth and accuracy of the foregoing representations, acknowledgments and agreements.

This document has been prepared on the basis that any offer of ordinary shares in any Member State will be made pursuant to an exemption under the Prospectus Directive from the requirement to publish a prospectus for offers of ordinary shares. Accordingly any person making or intending to make an offer in that Member State of ordinary shares which are the subject of the offering contemplated in this document may only do so in circumstances in which no obligation arises for the Company or any of the Underwriters to publish a prospectus pursuant to Article 3 of the Prospectus Directive in relation to such offer. Neither the Company nor the Underwriters have authorized, nor do they authorize, the making of any offer of ordinary shares in circumstances in which an obligation arises for the Company or the Underwriters to publish a prospectus for such offer.

For the purposes of this provision, the expression an "offer of ordinary shares to the public" in relation to any ordinary shares in any Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the ordinary shares to be offered so as to enable an investor to decide to purchase or subscribe for the ordinary shares, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State and the expression "Prospectus Directive" means Directive 2003/71/EC (as amended) and includes any relevant implementing measure in each Member State and the expression "2010 PD Amending Directive" means Directive 2010/73/EU.

The above selling restriction is in addition to any other selling restrictions set out below.

### **Notice to Prospective Investors in the United Kingdom**

In the United Kingdom, this document is being distributed only to, and is directed only at, and any offer subsequently made may only be directed at persons who are "qualified investors" (as defined in the Prospectus Directive) (i) who have professional experience in matters relating to investments falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (the "Order") and/or (ii) who are high net worth companies (or persons to whom it may otherwise be lawfully communicated) falling within Article 49(2)(a) to (e) of the Order (all such persons together being referred to as "relevant persons").

Each of the underwriters has represented and agreed that:

- (a) it has not made or will not make an offer of the securities to the public in the United Kingdom within the meaning of section 102B of the Financial Services and Markets Act 2000 (as amended) (referred to as "FSMA"), except to legal entities which are authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities or otherwise in circumstances which do not require the publication by us of a prospectus pursuant to the Prospectus Rules of the U.K. Financial Conduct Authority;
- (b) it has only communicated or caused to be communicated and will only communicate or cause to be communicated an invitation or inducement to engage in investment activity (within the meaning of section 21 of FSMA) to relevant persons; and

(c) it has complied with and will comply with all applicable provisions of FSMA with respect to anything done by it in relation to the securities in, from or otherwise involving the United Kingdom.

This document and its contents are confidential and should not be distributed, published or reproduced (in whole or in part) or disclosed by recipients to any other persons in the United Kingdom. Neither this document nor any of its contents must not be acted on or relied on in the United Kingdom by persons who are not relevant persons. In the United Kingdom, any investment or investment activity to which this document relates is only available to, and will be engaged in with, relevant persons.

#### **Notice to Prospective Investors in Switzerland**

The ordinary shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange ("SIX") or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the ordinary shares or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, the Company, the ordinary shares have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of ordinary shares will not be supervised by, the Swiss Financial Market Supervisory Authority, or FINMA, and the offer of ordinary shares has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes, or CISA. The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of ordinary shares.

#### **Notice to Prospective Investors in the Dubai International Financial Centre**

This prospectus relates to an Exempt Offer in accordance with the Offered Securities Rules of the Dubai Financial Services Authority ("DFSA"). This prospectus is intended for distribution only to persons of a type specified in the Offered Securities Rules of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus nor taken steps to verify the information set forth herein and has no responsibility for the prospectus. The ordinary shares to which this prospectus relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the shares offered should conduct their own due diligence on the ordinary shares. If you do not understand the contents of this prospectus you should consult an authorized financial advisor.

#### Notice to Prospective Investors in Australia

No placement document, prospectus, product disclosure statement or other disclosure document has been lodged with the Australian Securities and Investments Commission ("ASIC"), in relation to the offering. This prospectus does not constitute a prospectus, product disclosure statement or other disclosure document under the Corporations Act 2001 (the "Corporations Act"), and does not purport to include the information required for a prospectus, product disclosure statement or other disclosure document under the Corporations Act.

Any offer in Australia of the shares may only be made to persons (the "Exempt Investors") who are "sophisticated investors" (within the meaning of section 708(8) of the Corporations Act), "professional investors" (within the meaning of section 708(11) of the Corporations Act) or otherwise pursuant to one or more exemptions contained in section 708 of the Corporations Act so that it is lawful to offer the ordinary shares without disclosure to investors under Chapter 6D of the Corporations Act.

The ordinary shares applied for by Exempt Investors in Australia must not be offered for sale in Australia in the period of 12 months after the date of allotment under the offering, except in circumstances where disclosure to investors under Chapter 6D of the Corporations Act would not be required pursuant to an exemption under section 708 of the Corporations Act or otherwise or where the offer is pursuant to a disclosure document which complies with Chapter 6D of the Corporations Act. Any person acquiring ordinary shares must observe such Australian on-sale restrictions.

This prospectus contains general information only and does not take account of the investment objectives, financial situation or particular needs of any particular person. It does not contain any securities recommendations or financial product advice. Before making an investment decision, investors need to consider whether the information in this prospectus is appropriate to their needs, objectives and circumstances, and, if necessary, seek expert advice on those matters.

#### **Notice to Prospective Investors in Hong Kong**

The ordinary shares have not been offered or sold and will not be offered or sold in Hong Kong, by means of any document, other than (a) to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance; or (b) in other circumstances which do not result in the document being a "prospectus" as defined in the Companies Ordinance (Cap. 32) of Hong Kong or which do not constitute an offer to the public within the meaning of that Ordinance. No advertisement, invitation or document relating to the ordinary shares has been or may be issued or has been or may be in the possession of any person for the purposes of issue, whether in Hong Kong or elsewhere, which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to ordinary shares which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" as defined in the Securities and Futures Ordinance and any rules made under that Ordinance.

#### **Notice to Prospective Investors in Japan**

The ordinary shares have not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948, as amended) and, accordingly, will not be offered or sold, directly or indirectly, in Japan, or for the benefit of any Japanese Person or to others for re-offering or resale, directly or indirectly, in Japan or to any Japanese Person, except in compliance with all applicable laws, regulations and ministerial guidelines promulgated by relevant Japanese governmental or regulatory authorities in effect at the relevant time. For the purposes of this paragraph, "Japanese Person" shall mean any person resident in Japan, including any corporation or other entity organized under the laws of Japan.

#### **Notice to Prospective Investors in Singapore**

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of ordinary shares may not be circulated or distributed, nor may the ordinary shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore (the "SFA"), (ii) to a relevant person pursuant to Section 275(1), or any person pursuant to Section 275(1A), and in accordance with the conditions specified in Section 275, of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the ordinary shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

- (a) a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or
- (b) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,

securities (as defined in Section 239(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the ordinary shares pursuant to an offer made under Section 275 of the SFA except:

- (a) to an institutional investor or to a relevant person defined in Section 275(2) of the SFA, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;
- (b) where no consideration is or will be given for the transfer;
- (c) where the transfer is by operation of law;
- (d) as specified in Section 276(7) of the SFA; or
- (e) as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore.

#### Notice to Prospective Investors in Canada

The ordinary shares may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 *Prospectus Exemptions* or subsection 73.3(1) of the *Securities Act* (Ontario), and are permitted clients, as defined in National Instrument 31-103 *Registration Requirements*, *Exemptions and Ongoing Registrant Obligations*. Any resale of the ordinary shares must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 (or, in the case of securities issued or guaranteed by the government of a non-Canadian jurisdiction, section 3A.4) of National Instrument 33-105 *Underwriting Conflicts* (**NI 33-105**), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

#### LEGAL MATTERS

The validity of our ordinary shares and certain other matters of Cayman Islands law will be passed upon for us by Walkers, 190 Elgin Avenue, George Town, Grand Cayman KY1-9001, Cayman Islands. Certain other matters will be passed upon for us by Latham & Watkins LLP. Certain legal matters in connection with this offering will be passed upon for the underwriters by Cooley LLP.

#### **EXPERTS**

The consolidated financial statements of MeiraGTx Limited and Subsidiaries at December 31, 2017 and 2016, and for each of the two years in the period ended December 31, 2017, appearing in this Prospectus and Registration Statement have been audited by Ernst & Young LLP, independent registered public accounting firm, as set forth in their report (which contains an explanatory paragraph describing conditions that raise substantial doubt about the Company's ability to continue as a going concern as described in Note 1 to the consolidated financial statements) appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

#### **ENFORCEMENT OF CIVIL LIABILITIES**

We are incorporated under the laws of the Cayman Islands. We have been advised that there is some doubt as to the enforceability in the Cayman Islands, in original actions or in actions for enforcement of judgments of U.S. courts, of civil liabilities based solely on the federal securities laws of the United States. In addition, awards for punitive damages in actions brought in the United States or elsewhere may be unenforceable in the Cayman Islands. An award for monetary damages under the U.S. securities laws would be considered punitive if it does not seek to compensate the claimant for loss or damage suffered and is intended to punish the defendant. The enforceability of any judgment in the Cayman Islands will depend on the particular facts of the case as well as the laws and treaties in effect at the time. The United States and the Cayman Islands do not currently have a treaty providing for recognition and enforcement of judgments (other than arbitration awards) in civil and commercial matters.

We have appointed MeiraGTx, LLC as our agent to receive service of process with respect to any action brought against us in the United States District Court for the Southern District of New York under the federal securities laws of the United States or of any state in the United States or any action brought against us in the Supreme Court of the State of New York in the County of New York under the securities laws of the State of New York.

We have been advised by our Cayman Islands legal counsel that the courts of the Cayman Islands are unlikely (i) to recognize or enforce against us judgments of courts of the United States predicated upon the civil liability provisions of the federal securities laws of the United States or any state; and (ii) in original actions brought in the Cayman Islands, to impose liabilities against us predicated upon the civil liability provisions of the federal securities laws of the United States or any state, so far as the liabilities imposed by those provisions are penal in nature. In those circumstances, although there is no statutory enforcement in the Cayman Islands of judgments obtained in the United States, the courts of the Cayman Islands will recognize and enforce a foreign money judgment of a foreign court of competent jurisdiction without retrial on the merits based on the principle that a judgment of a competent foreign court imposes upon the judgment debtor an obligation to pay the sum for which judgment has been given provided certain conditions are met. For a foreign judgment to be enforced in the Cayman Islands, such judgment must be final and conclusive and for a liquidated sum, and must not be in respect of taxes or a fine or penalty, inconsistent with a Cayman Islands judgment in respect of the same matter, impeachable on the grounds of fraud or obtained in a manner, and or be of a kind the enforcement of which is, contrary to natural justice or the public policy of the Cayman Islands (awards of punitive or multiple damages may well be held to be contrary to public policy). A Cayman Islands Court may stay enforcement proceedings if concurrent proceedings are being brought elsewhere.

#### WHERE YOU CAN FIND MORE INFORMATION

We have filed with the Securities and Exchange Commission a registration statement on Form S-1 under the Securities Act with respect to the ordinary shares offered hereby. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement or the exhibits and schedules filed therewith. For further information about us and the ordinary shares offered hereby, we refer you to the registration statement and the exhibits and schedules filed thereto. Statements contained in this prospectus regarding the contents of any contract or any other document that is filed as an exhibit to the registration statement are not necessarily complete, and each such statement is qualified in all respects by reference to the full text of such contract or other document filed as an exhibit to the registration statement. Upon completion of this offering, we will be required to file periodic reports, proxy statements, and other information with the Securities and Exchange Commission pursuant to the Securities Exchange Act of 1934. You may read and copy this information at the Public Reference Room of the Securities and Exchange Commission, 100 F Street, N.E., Room 1580, Washington, District of Columbia. 20549. You may obtain information on the operation of the public reference rooms by calling the Securities and Exchange Commission at 1-800-SEC-0330. The Securities and Exchange Commission also maintains an Internet website that contains reports, proxy statements and other information about registrants, like us, that file electronically with the Securities and Exchange Commission. The address of that site is www.sec.gov.

Report of Independent Registered Public Accounting Firm

# INDEX TO CONSOLIDATED FINANCIAL STATEMENTS MEIRAGTX LIMITED AND SUBSIDIARIES FOR THE YEARS ENDED DECEMBER 31, 2016 AND 2017 AND FOR THE THREE MONTHS ENDED MARCH 31, 2017 AND 2018

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#### Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of MeiraGTx Limited and Subsidiaries

#### **Opinion on the Financial Statements**

We have audited the accompanying consolidated balance sheets of MeiraGTx Limited and Subsidiaries (the Company) as of December 31, 2017 and 2016, the related consolidated statements of operations and comprehensive loss, convertible preferred C shares, shareholders' deficit and cash flows for each of the two years in the period ended December 31, 2017, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2017 and 2016, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2017, in conformity with U.S. generally accepted accounting principles.

#### The Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses from operations, is subject to significant uncertainty with respect to its product development and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

#### **Basis for Opinion**

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2016.

Stamford, Connecticut
March 29, 2018, except for Note 6, as to which the date is May 11, 2018

### MEIRAGTX LIMITED AND SUBSIDIARIES CONSOLIDATED BALANCE SHEETS

	<u>December 31, 2016</u>	<u>December 31,</u> <u>2017</u>	March 31, 2018 (unaudited)	Pro Forma March 31, 2018 (unaudited)
<u>ASSETS</u>				
CURRENT ASSETS:				
Cash and cash equivalents	\$ 17,476,641	\$ 8,548,638	\$ 32,356,851	\$ 32,356,851
Prepaid expenses	1,212,183	1,961,243	2,816,413	2,816,413
Other current assets	400,956	965,233	841,172	841,172
Total Current Assets	19,089,780	11,475,114	36,014,436	36,014,436
Property and equipment, net	3,016,525	14,255,729	14,643,091	14,643,091
Restricted cash	444,844	123,376	123,376	123,376
TOTAL ASSETS	\$ 22,551,149	\$ 25,854,219	\$ 50,780,903	\$ 50,780,903
LIABILITIES, CONVERTIBLE PREFERRED C SHARES AND SH	AREHOLDERS'	DEFICIT		
CURRENT LIABILITIES:				
Accounts payable	\$ 1,474,213	\$ 7,055,380	\$ 5,184,508	\$ 5,184,508
Accrued expenses	4,018,103	9,332,944	6,657,257	6,657,257
Note payable	_	1,442,009	_	_
Warrant liability	_	2,679,633	2,010,225	_
Capitalized lease obligation—current portion	6,015	30,850	28,715	28,715
Due to Kadmon	543,038	861,030	6,493	6,493
Total Current Liabilities	6,041,369	21,401,846	13,887,198	11,876,973
Capitalized lease obligation	5,458	34,298	28,655	28,655
Deferred rent	588,491	266,290	241,488	241,488
Other liabilities	221,254	178,419	187,848	187,848
TOTAL LIABILITIES	6,856,572	21,880,853	14,345,189	12,334,964
COMMITMENTS				
CONVERTIBLE PREFERRED C SHARES				
Convertible Preferred C Shares 6,111,526, 19,428,037, 36,330,692 and 0 issued and outstanding at December 31, 2016, 2017, March 31, 2018 (unaudited), and pro forma March 31, 2018 (unaudited), respectively (liquidation preference of \$33,002,240, \$52,455,700, \$98,092,869 and 0 at December 31, 2016 and 2017, March 31, 2018 (unaudited) and pro forma March 31, 2018 (unaudited) respectively)  SHAREHOLDERS' DEFICIT:	32,833,660	51,338,631	97,351,080	_
Ordinary Shares, \$0.00001 nominal value	342	342	364	763
34,224,578 issued and 32,712,995 issued and outstanding at December 31, 2016				
34,254,578 issued and 33,821,221 issued and outstanding at December 31, 2017				
36,389,760 issued and 36,235,113 issued and outstanding at March 31, 2018 (unaudited)				
72,720,452 issued and outstanding at pro forma March 31, 2018 (unaudited)				
Capital in excess of nominal value	17,900,995	20,080,713	23,691,708	123,228,597
Accumulated other comprehensive loss	(661,112)	(2,022,477)	(2,780,242)	(2,780,242)
Accumulated deficit	(34,379,308)	(65,423,843)	(81,827,196)	(82,003,179)
Total Shareholders' Deficit	(17,139,083)	(47,365,265)	(60,915,366)	38,445,939
TOTAL LIABILITIES, CONVERTIBLE PREFERRED C SHARES AND				
SHAREHOLDERS' DEFICIT	\$ 22,551,149	\$ 25,854,219	\$ 50,780,903	\$ 50,780,903

### MEIRAGTX LIMITED AND SUBSIDIARIES CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	For the Ye Decem		Period	nree-Month s Ended ch 31,
	2016	2017	2017 (unaudited)	2018 (unaudited)
Operating expenses:			(unauditeu)	(unaddited)
General and administrative	6,026,529	9,325,017	2,148,540	11,122,016
Research and development	14,037,918	22,359,712	4,823,357	6,927,322
Total operating expenses	20,064,447	31,684,729	6,971,897	18,049,338
Loss from operations	(20,064,447)	(31,684,729)	(6,971,897)	(18,049,338)
Other non-operating income (expense)				
Foreign currency gain	265,543	1,676,117	149,249	978,624
Convertible note inducement expense	_	(553,500)	_	_
Change in fair value of warrant liability	_	(465,633)	_	669,408
Interest income	32,068	26,073	10,389	25,308
Interest expense	(25,440)	(42,863)	(8,126)	(27,355)
Net loss	(19,792,276)	(31,044,535)	(6,820,385)	(16,403,353)
Net loss attributable to the non-controlling interest in subsidiary	305,883			
Net loss attributable to MeiraGTx Limited shareholders	(19,486,393)	(31,044,535)	(6,820,385)	(16,403,353)
Other comprehensive loss	(671,391)	(1,361,365)	(130,895)	(757,765)
Comprehensive loss	(20,157,784)	(32,405,900)	(6,951,280)	(17,161,118)
Less: comprehensive loss attributable to noncontrolling interest	8,520	_	_	_
Comprehensive loss attributable to MeiraGTx Limited shareholders	\$(20,149,264)	\$ (32,405,900)	\$ (6,951,280)	\$ (17,161,118)
Net loss attributable to MeiraGTx Limited shareholders	\$(19,486,393)	\$(31,044,535)	\$ (6,820,385)	\$ (16,403,353)
Accretion on convertible preferred C shares	(85,425)	(806,963)	(22,761)	(664,718)
Adjusted net loss attributable to MeiraGTx Limited ordinary shareholders	\$(19,571,818)	\$(31,851,498)	\$ (6,843,146)	\$ (17,068,071)
Basic and diluted net loss per ordinary share attributable to ordinary shareholders	\$ (0.63)	\$ (0.96)	\$ (0.21)	\$ (0.49)
Weighted-average number of ordinary shares outstanding	31,098,591	33,269,157	32,851,408	34,647,368
Pro forma adjusted net loss attributable to MeiraGTx Limited ordinary shareholders (unaudited)		\$ (30,754,885)		\$ (17,072,761)
Pro forma basic and diluted net loss per ordinary share attributable to ordinary shareholders (unaudited)		\$ (0.42)		\$ (0.23)
Pro forma weighted-average number of ordinary shares outstanding—basic and diluted (unaudited)		73,288,947		74,667,158

## MEIRAGTX LIMITED AND SUBSIDIARIES CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED C SHARES AND SHAREHOLDERS' DEFICIT AS OF MARCH 31, 2018

		le Preferred <u>hares</u>				Sh Capital in Excess	areholders' Deficit <u>Accumulated</u> Other	Non-Controlling		
	Preferred C Shares	Amount	A Ordinary Shares	B Ordinary Shares	Amount	of Nominal Value	Comprehensive Income (Loss)	Interest in Subsidiary	Accumulated Deficit	Shareholders' Deficit
Balance at December 31, 2015 Issuance of A ordinary shares in connection with the Acquisition of	1,944,440	\$ 10,416,205	29,851,230	10,000	\$ 299	\$ 15,594,166	\$ 1,759		\$(14,892,915)	\$ (86,389)
BRI-Alzan, Inc. Issuance of A ordinary shares in connection with acquisition of			300,000	_	3	597,297	_	_	_	597,300
non-controlling interest of MeiraGTx UK II Limited	_	_	4,017,048	_	40	(1,104,141)	_	1,104,101	_	_
Issuance of convertible preferred C shares in connection with a										
payable Issuance of A ordinary shares in connection with a consulting	230,000	1,242,000	_	_		_	_	_	_	_
agreement Conversion of B ordinary shares into	_	_	46,300	_	_	92,137	_	_	_	92,137
A ordinary shares		_	10,000	(10,000)	_		_	_	_	_
Issuance of convertible preferred C shares in connection with a research agreement	59,259	319,999	_	_	_	_	_	_	_	_
Issuance of convertible preferred C shares, net of issuance costs	3,877,827	20,770,031	_	_	_	_	_	_	_	_
Accretion of issuance costs on convertible preferred C shares	_	85,425	_	_	_	(85,425)	_	_	_	(85,425)
Share-based compensation Foreign currency translation	_		_	_	_	2,806,961	(662,871)	(8,520)	_	2,806,961 (671,391)
Net loss for the year ended December 31, 2016						_	(002,071)	(305,883)	(19,486,393)	(19,792,276)
Balance at December 31, 2016 Exercised stock options	6,111,526	\$ 32,833,660	34,224,578 5,000		\$ 342	\$ 17,900,995 9,950	\$ (661,112)	\$ _	\$(34,379,308)	\$(17,139,083) 9,950
Issuance of A ordinary shares in connection with a license			3,000			3,330				3,330
agreement Extinguishment of convertible	_	_	25,000	_	_	17,000	_	_	_	17,000
preferred C shares, net of unaccreted issuance costs	(6,149,326)	(33,115,157)			_	33,115,157	_	_		33,115,157
Issuance of convertible preferred C shares in connection with extinguishment	12,298,652	33,206,360	_	_	_	(33,206,360)	_	_	_	(33,206,360)
Conversion of note payable into convertible preferred C shares	925,926	2,500,000	_	_	_	_	_	_	_	_
Issuance of convertible preferred C shares, net of warrants and issuance costs	6,241,259	15,198,008	_	_	_	_	_	_	_	_
Accretion of issuance costs on convertible preferred C shares	_	100,760	_	_	_	(100,760)	_	_	_	(100,760)
Accretion of warrants issued in connection with convertible		,				(,,				( 11, 11,
preferred C shares Share-based compensation	_	615,000	_	_	_	(615,000) 2,959,731	_	_	_	(615,000) 2,959,731
Foreign currency translation	_	_	_	_	_	2,939,731 —	(1,361,365)	_	_	(1,361,365)
Net loss for the year ended December 31, 2017									(31,044,535)	(31,044,535)
Balance at December 31, 2017 Issuance of convertible preferred C	19,428,037	51,338,631	34,254,578	_	\$ 342	\$ 20,080,713	\$ (2,022,477)	\$ —	\$(65,423,843)	\$(47,365,265)
shares in connection with payables Issuance of preferred C shares in connection with a license	502,270	1,356,129	_	_	_	_	_	_	_	_
agreement	51,852	140,000	_	_	_	_	_	_	_	_
Issuance of convertible preferred C shares, net of issuance costs	16,348,533	43,851,602	_	_	_	_	_	_	_	
Accretion of issuance costs on convertible preferred C shares Accretion of warrants issued in	_	94,445	_	_	_	(94,445)	_	_	_	(94,445)
connection with convertible						(======================================				(=== 0===)
preferred C shares Share-based compensation	_	570,273 —	2,135,182		22	(570,273) 4,275,713	_	_	_	(570,273) 4,275,735
Foreign currency translation Net loss for the three-month period	_	_	_	_	_	<u> </u>	(757,765)		_	(757,765)
ended March 31, 2018 Balance at March 31, 2018									(16,403,353)	(16,403,353)
(unaudited)	36,330,692	\$ 97,351,080	36,389,760		\$ 364	\$ 23,691,708	\$ (2,780,242)	<u> </u>	<u>\$(81,827,196)</u>	<u>\$(60,915,366)</u>

### MEIRAGTX LIMITED AND SUBSIDIARIES CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the Ye <u>Decem</u> 2016			nree-Month ed March 31, 2018 (unaudited)
Cash flows from operating activities:			,	,
Net loss	\$ (19,792,276)	\$ (31,044,535)	\$ (6,820,385)	\$ (16,403,353)
Adjustments to reconcile net loss to net cash used in operating activities:				
Issuance of shares for services	443,136	17,000	_	_
Share-based compensation expense	2,806,961	2,959,731	844,237	4,275,735
Foreign currency loss (gain)	(261,817)	(1,676,117)	(149,249)	(978,624)
Depreciation	243,081	679,177	179,878	458,836
Amortization of interest on asset retirement obligation Change in fair value of warrant liability	17,248	19,313 465,633	4,507	3,678 (669,408)
Convertible note inducement expense	_	553,500		(009,400)
Acquired research and development expense	597,300	333,300		
Issuance of note payable in connection with lease termination	J97,300 —	1,442,009		
Preferred C shares issued in connection with a license agreement	_		_	140,000
(Increase) decrease in operating assets:				1.0,000
Prepaid expenses and other current assets	(960,993)	(669,756)	(122,914)	(821,062)
Other current assets	(302,901)	(493,424)	(338,126)	153,773
Increase (decrease) in operating liabilities:	` '	` '	` '	
Accounts payable	453,130	4,728,491	842,876	171,045
Accrued expenses	1,333,796	4,969,619	(1,147,336)	(2,846,292)
Due to Kadmon	800,223	317,992	(128,974)	(854,537)
Deferred rent	255,160	(324,019)	389,928	(25,760)
Other liabilities			50,220	
Net cash used in operating activities	(14,367,952)	(18,055,386)	(6,395,338)	(17,395,969)
Cash flows from investing activities:				
Purchase of property and equipment	(2,593,584)	(10,535,717)	(1,737,520)	(1,210,452)
Net cash used in investing activities	(2,593,584)	(10,535,717)	(1,737,520)	(1,210,452)
Cash flows from financing activities:				
Payments on capitaized lease obligation	(5,480)	(24,388)	(1,452)	(7,779)
Proceeds from the issuance of note payable	_	2,500,000	_	_
Proceeds from the issuance of convertible preferred C shares, net of issuance costs  Proceeds from exercised stock options	20,762,682 —	16,854,653 9,950	197,995 —	43,851,602 —
Payment of note payable				(1,442,009)
Net cash provided by financing activities	20,757,202	19,340,215	196,543	42,401,814
Net increase (decrease) in cash, cash equivalents and restricted cash	3,795,666	(9,250,888)	(7,936,315)	23,795,393
Effect of exchange rate changes on cash	(421,240)	1,417	(11,109)	12,820
Cash, cash equivalents and restricted cash at beginning of period	14,547,059	17,921,485	17,921,485	8,672,014
Cash, cash equivalents and restricted cash at end of period	\$ 17,921,485	\$ 8,672,014	\$ 9,974,061	\$ 32,480,227
Supplemental disclosure of non-cash transactions: Fixed asset acquisition included in accounts payable and accrued expenses	\$ 301,655	\$ 415,650	\$ 766,107	\$ (811,095)
Conversion of note payable into convertible preferred C shares	\$	\$ 2,500,000	\$ -	\$ (011,055)
Issuance of convertible preferred C shares in connection with payables	\$ —	\$ —	\$ —	\$ 1,356,129
Capitalized lease obligation for equipment purchase	\$ 17,817	\$ 78,063	\$ —	\$ —
	<del></del>			
Issuance of convertible preferred C shares in settlement of due to Kadmon	\$ 1,242,000	<u> </u>	<u> </u>	<u> </u>
Issuance of A ordinary shares for acquisition of BRI-Alzan	\$ 597,300	<u>\$</u>	<u>\$</u>	<u>\$</u>
Issuance of convertible preferred C shares in connection with a research agreement	\$ 320,000	<u> </u>	<u> </u>	<u> </u>
Asset retirement obligation in connection with a lease	\$ 205,659	<u>\$ (75,011)</u>	<u>\$</u>	<u>\$</u>
Supplemental disclosure of cash flow information:  Cash paid for interest	\$ —	\$ 20,894	\$ 257	\$ 31,531

### MEIRAGTX LIMITED AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

#### 1. Principal Business Activity:

#### The Company

MeiraGTx Limited (the "Company" or "Meira Limited"), a limited company under the laws of England and Wales formed on March 20, 2015, is a clinical-stage biotech company developing novel gene therapy treatments for a wide range of inherited and acquired disorders for which there are no effective treatments available. The Company is focused on developing therapies for ocular diseases, including rare inherited blindness as well as Xerostomia following radiation treatment for head and neck cancers and neurodegenerative diseases such as amyothrophic lateral sclerosis ("ALS").

On April 24, 2015, the Company acquired certain assets held by Kadmon Corporation, LLC ("Kadmon") and began operations. In connection with the transfer of these assets, the Company entered into a transition services agreement with Kadmon whereby Kadmon would provide office and laboratory facilities as well as certain other personnel support activities (see Note 15).

On April 27, 2015, the Company entered into a worldwide collaborative development and license agreement ("CDLA") with Athena Vision Limited ("Athena") to develop and commercialize pre-clinical gene therapies for certain ocular indications. Concurrent with the execution of the CDLA, the Company and Athena entered into a shareholders' agreement in which the Company issued 2,760,000 A ordinary shares ("Ordinary Shares") and 250 B ordinary shares, which were converted into Ordinary Shares, to the shareholders of Athena in exchange for a 60% equity interest in Athena.

On April 8, 2016, the Company issued 4,017,048 Ordinary Shares to the shareholders of Athena in exchange for the remaining 40% equity interest in Athena and changed the name of Athena to MeiraGTx UK II Limited ("MeiraGTx UK II").

#### **Basis of Presentation**

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative United States generally accepted accounting principles as found in the Accounting Standards Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB").

On April 27, 2015, the Company acquired as 60% interest in MeiraGTx UK II. As such, a non-controlling interest was recorded on the date of acquisition through April 8, 2016, when the Company acquired the remaining 40% interest in MeiraGTx UK II.

#### Liquidity

The consolidated financial statements of the Company have been prepared on a going-concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. Accordingly, the financial statements do not include any adjustments that might be necessary should the Company be unable to continue in existence. The Company has not generated any revenues and has not yet achieved profitable operations. There is no assurance that profitable operations, if ever achieved, could be sustained on a continuing basis. In addition, development activities, clinical and preclinical testing, and commercialization of the Company's product candidates will require significant additional financing. The Company's accumulated deficit at December 31, 2017 and March 31, 2018 totaled \$65,423,843 and \$81,827,196,

### MEIRAGTX LIMITED AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

respectively, and management expects to incur substantial and increasing losses in future periods. The success of the Company is subject to certain risks and uncertainties, including among others, uncertainty of product development; competition in the Company's field of use; uncertainty of capital availability; uncertainty in the Company's ability to enter into agreements with collaborative partners; dependence on third parties; and dependence on key personnel. The Company has not generated positive cash flows from operations, and there are no assurances that the Company will be successful in obtaining an adequate level of financing for the development and commercialization of its product candidates. These factors raise substantial doubt about the Company's ability to continue as a going concern. The Company does not have adequate cash on hand to cover its anticipated expenses past the next 12 months. If the Company fails to raise a significant amount of capital or enter into a strategic transaction, it may need to significantly curtail operations, cease operations or seek federal bankruptcy protection in the near future. These conditions raise substantial doubt about its ability to continue as a going concern.

As of December 31, 2017, the Company had cash and cash equivalents in the amount of \$8,548,638, which consisted of depository accounts. From January 1, 2018 through March 29, 2018, the Company issued 16,943,396 convertible preferred C shares ("Preferred Shares") for gross proceeds of \$45,747,173. The Company estimates that its cash and cash equivalents on hand at December 31, 2017 and the proceeds from the issuance of Preferred Shares from January 1, 2018 through March 29, 2018 will cover its expenses into the fourth quarter of 2018.

As of March 31, 2018, the Company had cash and cash equivalents in the amount of \$32,356,851, which consisted of depository accounts. From April 1, 2018 through April 30, 2018, the company issued 4,597,637 Preferred Shares for gross proceeds of \$12,413,619. The Company estimates that its cash and cash equivalents on hand at March 31, 2018 and the proceeds from the issuance of Preferred Shares from April 1, 2018 through April 30, 2018 will cover its expenses into the first quarter of 2019.

In order to provide the Company with the cash resources necessary to fund operations, the Company will continue its efforts to raise additional capital through either a private or public equity placement or strategic transaction in the near future.

If the Company is unable to raise additional funds, it will need to do one or more of the following:

- license third parties to develop and commercialize products or technologies that it would otherwise seek to develop and commercialize itself;
- seek strategic alliances or business combinations;
- attempt to sell the Company;
- · cease operations; or
- declare bankruptcy.

#### Risks and Uncertainties

The Company operates in an industry that is subject to intense competition, government regulation and rapid technological change. The Company's operations are subject to significant risk and uncertainties including financial, operational, technological, regulatory and other risks, including the potential risk of business failure.

### MEIRAGTX LIMITED AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

The Company's limited capital resources and operations to date have been funded primarily with the proceeds from private equity.

#### Reverse Stock Split

The Company's shareholders approved a 10:1 stock split, effective February 2, 2016. All share information presented in these financial statements and accompanying footnotes have been retroactively adjusted to reflect the increased number of shares resulting from this action.

#### 2. Summary of Significant Accounting Policies:

#### Consolidation

The accompanying condensed consolidated financial statements include the accounts of Meira Limited and its wholly owned subsidiaries:

MeiraGTx, LLC, a Delaware corporation, ("Meira LLC");

BRI-Alzan, Inc., a Delaware corporation ("BRI-Alzan");

MeiraGTx B.V., a Netherlands corporation ("Meira BV");

MeiraGTx UK II Limited, ("Meira UK II"), a limited company under the laws of England and Wales;

MeiraGTx UK Limited ("Meira UK"), a limited company under the laws of England and Wales.

All intercompany balances and transactions between the consolidated companies have been eliminated in consolidation.

#### **Unaudited Interim Financial Statements**

The accompanying interim consolidated balance sheet as of March 31, 2018, the consolidated statements of operations and comprehensive loss and consolidated statements of cash flows for the three months ended March 31, 2017 and 2018, the statement of convertible preferred C shares and stockholders' deficit for the three months ended March 31, 2018, and the financial data and other information disclosed in these notes related to the three months ended March 31, 2017 and 2018 are unaudited. The unaudited interim financial statements have been prepared on the same basis as the audited annual financial statements, and, in the opinion of management, reflect all adjustments, consisting of normal recurring adjustments, necessary for the fair presentation of the Company's financial position as of March 31, 2018, and the results of its operations and its cash flows for the three month ended March 31, 2017 and 2018. The results as of and for the three months ended March 31, 2018 are not necessarily indicative of the results to be expected for the year ending December 31, 2018, any other interim periods, or any future year or period.

#### Unaudited Pro Forma Financial Information

The accompanying unaudited pro forma consolidated balance sheet as of March 31, 2018 has been prepared to give effect to (1) the automatic conversion of all outstanding shares of convertible preferred C shares into ordinary shares, based on a conversion ratio currently in effect, which is 1:1, (2) the vesting of certain previously unvested restricted shares upon the completion of an initial public offering and (3) the reclassification of the warrant liability into capital in excess of nominal value. The ordinary shares issuable and the proceeds expected to be received in the initial public offering and ordinary shares to be granted on the effectiveness of this registration statement to the CEO and COO are excluded from such pro forma financial information.

### MEIRAGTX LIMITED AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

In the accompanying consolidated statements of operations, the unaudited pro forma adjusted net loss attributable to MeiraGTx Limited ordinary shareholders used in the calculation of unaudited pro forma basic and diluted net loss per share attributable to ordinary shareholders does not include the effects of accretion on convertible preferred C shares or the remeasurement of the warrants to purchase convertible preferred C shares because it assumes that the conversion of convertible preferred C shares into ordinary shares and conversion of convertible preferred C share warrant into ordinary shares occurred on the beginning of the reporting period for the year ended December 31, 2017.

#### Unaudited Pro Forma Net Loss per Share

Pro forma basic and diluted net loss per share attributable to ordinary shareholders has been computed to give effect to the conversion of all outstanding convertible preferred shares into ordinary shares. The unaudited pro forma net loss per share does not include the shares expected to be sold and related proceeds to be received from the initial public offering. The unaudited pro forma net loss per share for the twelve months ended December 31, 2017 was computed using the weighted-average number of shares of ordinary shares outstanding, including the pro forma effect of the conversion of all outstanding shares of convertible preferred shares into ordinary shares, including warrant to purchase convertible preferred C shares, as if such conversion had occurred January 1, 2017.

#### **Use of Estimates**

Management considers many factors in selecting appropriate financial accounting policies and controls, and in developing the estimates and assumptions that are used in the preparation of these consolidated financial statements. Management must apply significant judgment in this process. In addition, other factors may affect estimates, including expected business and operational changes, sensitivity and volatility associated with the assumptions used in developing estimates, and whether historical trends are expected to be representative of future trends. The estimation process often may yield a range of potentially reasonable estimates of the ultimate future outcomes and management must select an amount that falls within that range of reasonable estimates. This process may result in actual results differing materially from those estimated amounts used in the preparation of the financial statements if these results differ from historical experience, or other assumptions do not turn out to be substantially accurate, even if such assumptions are reasonable when made. In preparing these consolidated financial statements, management used significant estimates in the following areas, among others: valuation of Ordinary Shares issued for the acquisition of assets, the accounting for research and development costs, warrants, share based compensation and accrued expenses.

#### Subsequent Events

The Company considers events or transactions that occur after the balance sheet date but before the financial statements are issued to provide additional evidence relative to certain estimates or to identify matters that require additional disclosure. Subsequent events were reviewed through the date of this filing for the years ended December 31, 2016 and 2017 and for the interim financial statements and disclosures for the three months ended March 31, 2017 and 2018. See Note 18 for additional information.

#### Cash and Cash Equivalents

The Company considers all highly liquid instruments with an original maturity of 90 days or less at the time of purchase to be cash equivalents. Cash and cash equivalents consist of deposits that are readily convertible into cash.

### MEIRAGTX LIMITED AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

#### **Warrant Liability**

During 2017, the Company issued warrants to purchase Preferred Shares to certain investors. Due to the potential redemption feature of the underlying Preferred Shares, the warrants have been classified as a liability. Liability accounting requires that the fair value of warrants be remeasured each reporting period with changes recorded in the statements of operations and comprehensive loss. These Preferred Shares warrants will remain outstanding until the exercise or expiration of the warrants or the completion of a qualified IPO, at which time the warrant liability will be remeasured to fair value and reclassified to additional paid-in capital.

#### **Financial Instruments**

The carrying value of prepaid expenses, other current assets, accounts payable, accrued expenses, notes payable and amounts due to an affiliate reported in the consolidated balance sheets equal or approximate fair value due to their short maturities.

#### Fair Value Measurements

Fair value is defined as the price that would be received upon sale of an asset or paid upon transfer of a liability in an orderly transaction between market participants at the measurement date and in the principal or most advantageous market for that asset or liability. The fair value should be calculated based on assumptions that market participants would use in pricing the asset or liability, not on assumptions specific to the entity. In addition, the fair value of liabilities should include consideration of non-performance risk including our own credit risk.

The Company follows ASC Topic 820, *Fair Value Measurements and Disclosures*, or ASC 820, for application to financial assets. In addition to defining fair value, the standard expands the disclosure requirements around fair value and establishes a fair value hierarchy for valuation inputs. The hierarchy prioritizes the inputs into three levels based on the extent to which inputs used in measuring fair value are observable in the market. Each fair value measurement is reported in one of the three levels which are determined by the lowest level input that is significant to the fair value measurement in its entirety. These levels are:

- Level 1: Observable inputs such as quoted prices in active markets for identical assets the reporting entity has the ability to access as of
  the measurement date;
- · Level 2: Inputs, other than the quoted prices in active markets, that are observable either directly or indirectly; and
- Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

### MEIRAGTX LIMITED AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

The table below represents the values of the Company's financial assets and liabilities that are required to be measured at fair value on a recurring basis:

	Fair Value Measurement Using:				
	December 21	Significant	Significant Other	Significant Unobservable	
Description	December 31, 2016	Observable Inputs (Level 1)	Observable Inputs (Level 2)	(Level 3)	
Restricted cash	\$ 444,844	\$ 444,844	\$ <u>(======</u> —	\$	
Total	\$ 444,844	\$ 444,844	\$ —	<del>\$</del> —	
	<del></del>				
		Fair Value Mea	surement Using:		
		Significant	Significant Other	Significant	
Description	December 31, 2017	Observable Inputs	Observable Inputs	Unobservable	
Description Restricted cash	\$ 123,376	(Level 1) \$ 123,376	(Level 2) —	(Level 3) \$ —	
	+,	\$ 125,570	<b>y</b> —	~	
Warrants	2,679,633			2,679,633	
Total	\$2,803,009	\$ 123,376	\$ —	\$ 2,679,633	
		Fair Value Mea	surement Using:		
		Significant	Significant Other	Significant	
	March 31,	Observable Inputs	Observable Inputs	Unobservable	
Description	2018	(Level 1)	(Level 2)	(Level 3)	
Restricted cash	\$ 123,376	\$ 123,376	\$ —	\$ —	
Warrants	2,010,225			2,010,225	
Total	\$2,133,601	\$ 123,376	\$	\$ 2,010,225	

The table below represents a rollforward of the assets and liabilities that are required to be measured at fair value on a recurring basis from December 31, 2015 to March 31, 2018:

	Significant Observable Inputs (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Balance as of December 31, 2015	\$	\$	\$
Restriction of cash	444,844	_	_
Balance as of December 31, 2016	444,844		
Cash released from restriction	(321,468)	_	_
Fair value of warrants issued	_	_	2,214,000
Change in fair value of warrants	_	_	465,633
Balance as of December 31, 2017	123,376		2,679,633
Change in fair value of warrants	_	_	(669,408)
Balance as of March 31, 2018	\$ 123,376	\$ —	\$ 2,010,225

The warrants are classified as liabilities because the underlying Preferred Shares have a redemption feature in the event of a change of control of the Company.

The fair values of the warrants were estimated using the Black-Scholes valuation model with the following assumptions:

	<b>September 21, 2017</b>	<b>November 2, 2017</b>	December 31, 2017	March 31, 2018
Risk-free interest rate	1.38%	1.53%	1.72%	1.86%
Expected volatility	80%	80%	80%	80%
Expected dividend yield	0	0	0	0
Expected life	18 months	18 months	9 months	5.5 months

For the unobservable inputs for the warrants, the expected volatility was determined at each measurement date by taking an average of the volatility of other publicly-traded peer biotechnology companies. The expected life was determined at each measurement date based upon the Company's estimate of the time until the Company has a conversion event, as described in Note 11.

The fair value of the Preferred Shares was based upon recent issuances of the Company's Preferred Shares on or about these dates.

The estimated fair values of the Company's warrants are not necessarily indicative of the amounts that would be realized in a current market exchange. The determination of the fair value of the warrants are sensitive to changes in in the assumptions used and a change in those inputs could result in a significantly higher or lower fair value measurement. If the volatility were to increase or the expected life were to increase, the fair value of the warrant would increase. Conversely, if the volatility were to decrease or the expected life were to decrease, the fair value of the warrant would decrease

#### Convertible Preferred C Shares

The Preferred Shares are not redeemable. However, in the event of a Sale (as defined in the Company's Articles of Association), which would include a change of control that is outside of the Company's control, the Preferred Shares are entitled to receive a payment which is equal to their liquidation value. The feature is being accounted for as a redemption under ASC 480.

The Company is accounting for its Preferred Shares under the requirements of ASC 480 which establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. The carrying value of the Preferred Shares is presented in as temporary equity and is increased by periodic accretions so that the carrying amount will equal the redemption amount at the estimated date that the Preferred Shares will be converted into Ordinary Shares. These increases are affected through charges against additional paid-in capital, to the extent it is available, or accumulated deficit. For all Preferred Shares issuance, the difference between the amount invested by the holders of the Preferred Shares, net of issuance costs and the initial fair value of warrants issued in connection with the Preferred Shares (if applicable) and the liquidation value of the Preferred Shares is recorded as accretion over the estimated life of the Preferred Shares. The accretion is added to net loss to arrive at the net loss available to Ordinary Shareholders in the calculation of loss per Ordinary Share.

#### Concentrations of Credit Risk

The Company maintains its cash and cash equivalents primarily in depository and money market accounts within two large financial institutions in the United States and one large financial institution in the United Kingdom. Cash balances deposited at these major financial banking institutions exceed the insured limit. The Company has not experienced any losses on its bank deposits and believes these deposits do not expose the Company to any significant credit risk.

#### Property and Equipment, Net

Property and equipment (consisting of computer, office, laboratory and manufacturing equipment, furniture and fixtures and leasehold improvements) are stated at cost, net of accumulated depreciation. Depreciation is calculated using the straight-line method over the estimated useful lives of the respective assets. Leasehold improvements are depreciated over the lesser of their useful lives or the life of the lease (see Note 5).

The estimated useful lives of the asset categories are set forth in the table below:

Asset Category	Useful Lives
Computer and office equipment	3 years
Laboratory equipment	5 years
Manufacturing equipment	7 years
Furniture and fixtures	5 years
Leasehold improvements	lesser of useful
	life or remaining
	term of lease

Expenditures for leasehold improvements are capitalized, and expenditures for maintenance and repairs are expensed to operations as incurred.

ASC Topic 360, *Property, Plant and Equipment*, addresses the financial accounting and reporting for impairment or disposal of long-lived assets. The Company reviews the recorded values of long-lived assets for impairment whenever events or changes in business circumstances indicate that the carrying amount of an asset or group of assets may not be fully recoverable. The Company recorded no impairment charges in any of the periods presented.

#### **Net Loss per Ordinary Share**

Basic net loss per Ordinary Share is computed by dividing net loss attributable to the Company's shareholders by the weighted average number of shares of the Company's Ordinary Shares assumed to be outstanding during the period of computation. Diluted net loss per ordinary share is computed similar to basic net loss per share except that the denominator is increased to include the number of additional Ordinary Shares that would have been outstanding if the potential ordinary shares had been issued at the beginning of the year and if the additional ordinary shares were dilutive (treasury stock method) or the two-class method, whichever is more dilutive. For all period presented, basic and diluted net loss per Ordinary Share are the same, as any additional Ordinary Share equivalents would be anti-dilutive (see Note 12).

#### **Income Taxes**

Income taxes are recorded in accordance with ASC Topic 740, *Income Taxes*, or ASC 740, which provides for deferred taxes using an asset and liability approach. The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Realization of net deferred tax assets is dependent on future taxable income. Valuation allowances are provided, if based upon the weight of available evidence, it is more likely than not that some, or all, of the deferred tax assets will not be realized. Realization of net deferred tax assets is dependent on future taxable income (see Note 14).

### MEIRAGTX LIMITED AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

The Company accounts for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances. As of December 31, 2016 and 2017, the Company does not have any significant uncertain tax positions.

The Company is required to estimate income taxes in each of the jurisdictions in which it operates.

The Company's reserves related to taxes are based on a determination of whether and how much of a tax benefit taken by the Company in its tax filings or positions is more likely than not to be realized. As of December 31, 2017, the Company had no unrecognized tax benefits or related interest and penalties accrued.

In the United States, on December 22, 2017, the "Tax Cuts and Jobs Act" (the "Act") was signed into law. Substantially all of the provisions of the Act are effective for taxable years beginning after December 31, 2017. The Act includes significant changes to the Internal Revenue Code of 1986 (as amended, the "Code"), including amendments which significantly change the taxation of individuals, and business entities. The Act contains numerous provisions impacting the Company, the most significant of which reduces the Federal corporate statutory tax rate from 34% to 21%.

The staff of the U.S. Securities and Exchange Commission ("SEC") has recognized the complexity of reflecting the impacts of the Act, and on December 22, 2017 issued guidance in Staff Accounting Bulletin 118 ("SAB 118"), which clarifies accounting for income taxes under ASC 740 if information is not yet available or complete and provides for up to a one year period in which to complete the required analyses and accounting (the measurement period). SAB 118 describes three scenarios (or "buckets") associated with a company's status of accounting for income tax reform: (1) a company is complete with its accounting for certain effects of tax reform, (2) a company is able to determine a reasonable estimate for certain effects of tax reform and records that estimate as a provisional amount, or (3) a company is not able to determine a reasonable estimate and therefore continues to apply ASC 740, based on the provisions of the tax laws that were in effect immediately prior to the Act being enacted.

The various provisions under the Act deemed most relevant to the Company have been considered in preparation of its financial statements as of December 31, 2017. The Company has made a reasonable estimate for certain effects of tax reform and has recorded provisional amounts as part of its income tax provision. To the extent that clarifications or interpretations materialize in the future that would impact upon the effects of the Act incorporated into the December 31, 2017 financial statements, those effects will be reflected in the future as or if they materialize.

Through March 31, 2018, the Company did not have any significant adjustments to the provisional amounts. The Company will continue to analyze the provisional amounts, which are still subject to change during the measurement period, and the Company anticipates further guidance on accounting interpretations from the FASB and application of the law from the Department of the Treasury.

#### **Research and Development**

Research and development costs are charged to expense as incurred. These costs include, but are not limited to, employee-related expenses, including salaries, benefits and travel of the Company's research and development personnel; expenses incurred under agreements with contract research organizations and investigative sites that conduct clinical and preclinical studies and manufacture the drug product for the clinical

### MEIRAGTX LIMITED AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

studies and preclinical activities; acquisition of in-process research and development; facilities; supplies; rent, insurance, certain legal fees, stock-based compensation, depreciation and other costs associated with clinical and preclinical activities and regulatory operations. Refundable research and development tax credits received are recorded as an offset to these costs.

Costs for certain development activities, such as outside research programs funded by the Company, are recognized based on an evaluation of the progress to completion of specific tasks with respect to their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the financial statements as prepaid or accrued research and development expense, as the case may be.

#### **Share Based Compensation Expense**

**Options** 

The Company grants share options to employees, non-employee members of the Company's board of directors and non-employee consultants as compensation for services performed. Employee and non-employee members of the board of directors' awards of share-based compensation are accounted for in accordance with ASC 718, *Compensation - Stock Compensation* or ASC 718. ASC 718 requires all share-based payments to employees and non-employee directors, including grants of share options, to be recognized in the Statement of Operations and Comprehensive Loss based on their grant date fair values. The grant date fair value of share options is estimated using the Black-Scholes option valuation model.

Using this model, fair value is calculated based on assumptions with respect to (i) the fair value of the Company's Ordinary Shares on the grant date; (ii) expected volatility of the Company's Ordinary Share price, (iii) the periods of time over which employees and members of the Company's board of directors are expected to hold their options prior to exercise (expected term), (iv) expected dividend yield on the Company's Ordinary Shares, and (v) risk-free interest rates.

As there has been no public market for the Company's Ordinary Shares to date, the estimated fair value of the Ordinary Shares has been determined by the Company's board of directors as of the date of each option grant, with input from management, considering the most recently available third-party valuations of Ordinary Shares and the board of directors' assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent valuation through the date of the grant.

The third party estimated the fair value of the equity using a special case of the market approach known as the backsolve method. The backsolve method was used to solve for the implied total equity value based on the Company's recent Series C financing round. Consideration was given to the rights and preferences of each of Company's classes of equity and the expected time to a liquidity event. An option pricing allocation method, or OPM, was selected to allocate the total equity value. The OPM treats ordinary shares and preferred shares as call options on the total equity value of a company, with exercise prices based on the value thresholds at which the allocation among the various holders of a company's securities changes. Under this method, the Ordinary Shares have value only if the funds available for distribution to stockholders exceeded the value of the Preferred Share liquidation preference at the time of the liquidity event, such as a strategic sale or a merger. These third-party valuations resulted in a valuation of the Company's Ordinary Shares of \$1.95, \$0.68, \$1.45 and \$1.55 per share as of December 31, 2016, September 15, 2017, December 31, 2017, and March 31, 2018, respectively.

The assumptions underlying these valuations represented management's best estimate, which involved inherent uncertainties and the application of management's judgment. As a result, if the Company had used

### MEIRAGTX LIMITED AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

different assumptions or estimates, the fair value of its Ordinary Shares and its share-based compensation expense could have been materially different.

Since Company's Ordinary Shares have not been traded on a public exchange, the Company believes that it does not have sufficient company-specific information available to determine the expected term based on its historical data. As a result, the expected term of share options granted to employees and members of the Company's board of directors is determined using the average of the vesting period and contractual life of the option, an accepted method for the Company's option grants under the SEC's Staff Accounting Bulletin No. 107 and No. 110, *Share-Based Payment*.

Similarly, the Company believes that its future volatility will differ materially during the expected term from the volatility that would be calculated from its historical share prices to date. Consequently, expected volatility is based on an analysis of guideline companies in accordance with ASC 718. The expected dividend yield is zero as the Company has never paid dividends and does not currently anticipate paying any in the foreseeable future. Risk-free interest rates are based on quoted U.S. Treasury rates for securities with maturities approximating the option's expected term.

As of January 1, 2016, the Company early adopted ASU 2016-09, *Improvements to Employee Share-Based Payment Accounting*, and accounts for forfeitures as they occur from that date. Additionally, excess tax benefits and deficiencies will be recognized as income tax expense or benefit in the income statement. There was no cumulative effect adjustment as the Company did not issue any options prior to January 1, 2016 (see *Accounting Pronouncements Recently Adopted*, below).

The Company accounts for options granted to non-employee consultants under ASC 505-50, *Equity-Based Payments to Non-Employees*. As such, the Company estimates the fair value of each such option using the Black-Scholes model, with the expected term of share options granted to non-employees initially equal to the options' maximum contractual life of ten years, at issuance. On each subsequent reporting date until performance is complete, the Company revalues all outstanding options granted to non-employee consultants during the vesting period of each tranche. Under ASC 505-50, upon re-measurement of each award, income or expense is recognized during its vesting term. Compensation cost relating to awards with service-based graded vesting schedules is recognized as general and administrative and research and development expenses in the consolidated statements of operations and comprehensive loss using the straight-line method.

#### Restricted Shares

In connection with certain service agreements and research agreements, the Company has granted restricted ordinary shares as compensation. The shares are recognized in the statements of operations and comprehensive loss based on their grant date fair values. Compensation cost relating to share grants with service-based graded vesting schedules is recognized based on the vesting schedule.

#### Leases

The Company recognizes rent expense for operating leases on a straight-line basis over the term of the lease, beginning on the date the Company takes possession of the property. Rent expense includes the base amounts stated in the lease agreement as well as the effect of reduced or free rent and rent escalations. At lease inception, the Company determines the lease term by assuming the exercise of those renewal options that are reasonably assured because of the significant economic penalty that exists for not exercising those options. The exercise of renewal options is at the Company's sole discretion. The expected lease term is one of the factors used to determine whether a lease is classified as operating or capital and is used to calculate the straight-line rent

### MEIRAGTX LIMITED AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

expense. The difference between the cash paid to the landlord and the amount recognized as rent expense on a straight-line basis is included in deferred rent and classified within long-term liabilities. Lease incentives made by landlords to or on behalf of the Company for leasehold improvements are recorded as deferred rent and classified as long-term liabilities.

The Company uses estimates to determine the amount of asset retirement obligation at the end of the lease terms and discounts such asset retirement obligations using an estimated discount rate. Interest on the discounted asset retirement obligation is amortized over the term of the lease using the effective interest method and is recorded as interest expense in the consolidated statements of operations and comprehensive loss.

#### **Asset Retirement Obligation**

Accounting for Asset Retirement Obligations requires legal obligations associated with the retirement of long-lived assets to be recognized at fair value when incurred and capitalized as part of the related long-lived asset. In the absence of quoted market prices, we estimate the fair value of our asset retirement obligations using Level 3 present value techniques, in which estimates of future cash flows associated with retirement activities are discounted using a credit-adjusted risk-free rate. Asset retirement obligations currently reported as other liabilities on our Consolidated Balance Sheet were measured during a period of historically low interest rates. The impact on measurements of new asset retirement obligations using different rates in the future may be significant.

The Company uses estimates to determine the amount of the asset retirement obligations at the end of the lease term and discounts such asset retirement obligations using an estimated discount rate. Interest on the discounted asset retirement obligation is amortized over the term of the lease using the effective interest method and is recorded as interest expense in the consolidated statements of operations and comprehensive loss.

The change in asset retirement obligations is as follows:

	For the year end 2016	led December 31, 2017	For the three months end March 31, 2018	ded
Balance at beginning of year	\$ —	\$ 221,254	\$ 178,4	119
Inception of asset retirement obligation	205,659	_	_	_
Amortization of interest	17,248	19,313	3,6	578
Change in estimate	_	(75,011)	_	_
Effects of exchange rate	(1,653)	12,863	5,7	<sup>7</sup> 51
Balance at end of year	\$ 221,254	\$ 178,419	\$ 187,8	348

#### **Other Comprehensive Loss**

Comprehensive loss is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources.

#### Foreign Currencies

The Company's consolidated financial statements are presented in U.S. dollars, the reporting currency of the Company. The financial position and results of operations of MeiraGTx UK II and MeiraGTx B.V. are measured using the foreign subsidiaries' local currency as the functional currency. MeiraGTx UK II cash

accounts holding U.S. dollars are remeasured based upon the exchange rate at the date of remeasurement with the resulting gain or loss included in the consolidated statements of operations and comprehensive loss. Expenses of such subsidiaries have been translated into U.S. dollars at average exchange rates prevailing during the period. Assets and liabilities have been translated at the rates of exchange on the consolidated balance sheet dates. The resulting translation gain and loss adjustments are recorded directly as a separate component of Shareholders' equity and as Other comprehensive loss on the consolidated statements of operations and comprehensive loss.

#### **Segment Information**

Management has concluded it has a single reporting segment for purposes of reporting financial condition and results of operations.

The following table summarizes non-current assets by geographical area:

	December 31, 2016	December 31, 2017	March 31, 2018
United States	\$ 1,081,522	\$ 436,463	\$ 411,254
United Kingdom	2,379,847	13,942,642	14,355,213
	\$ 3,461,369	\$ 14,379,105	\$ 14,766,467

Accounting Pronouncements Recently Adopted

In May 2017, the FASB issued ASU No. 2017-09, *Compensation—Stock Compensation (Topic 718)*, *Scope of Modification Accounting*. ASU 2017-09 provides guidance on the types of changes to the terms or conditions of share-based payment awards to which an entity would be required to apply modification accounting. ASU 2017-09 is applied prospectively to awards modified on or after the effective date. The Company adopted ASU 2017-09 on January 1, 2018. There were no modifications that had an impact on the Company's consolidated financial statements.

In January 2017, the FASB issued ASU No. 2017-01, *Business Combinations (Topic 805), Clarifying the Definition of a Business*, or ASU 2017-01, that clarifies the definition of a business to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. ASU 2017-01 requires an entity to evaluate if substantially all of the fair value of the gross assets acquired or disposed of is concentrated in a single identifiable asset or a group of similar identifiable assets; if so, the set of transferred assets and activities is not a business. ASU 2017-01 also requires a business to include at least an input and one substantive process that together significantly contribute to the ability to create output and removes the evaluation of whether a market participant could replace missing elements. ASU 2017-01 should be applied prospectively and is effective for annual periods beginning after December 15, 2017 and interim periods within those annual periods. The adoption of ASU 2017-01 on January 1, 2018 did not have a material effect on its financial position, results of operations or cash flows.

In May 2016, the FASB issued ASU No. 2016-12, *Revenue from Contracts with Customers (Topic 606)*, *Narrow-Scope Improvements and Practical Expedients*, or ASU 2016-12, which amends guidance in the new revenue standard, ASU No. 2014-09 *Revenue from Contracts with Customers (Topic 606)*, or ASU 2014-09, on collectability, noncash consideration, presentation of sales tax and transition. The amendments in ASU 2016-12 are effective for annual reporting periods beginning after December 15, 2017 (i.e., January 1, 2018), including interim periods within those reporting periods, which is the same as for ASU 2014-09, as amended by ASU No. 2015-14, *Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date*, or ASU 2015-14. In April 2016, the FASB issued ASU No. 2016-10, *Revenue from Contracts with* 

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Customers (Topic 606), Identifying Performance Obligations and Licensing, or ASU 2016-10, which clarifies the principle for determining whether a good or service is "separately identifiable" from other promises in the contract and, therefore, should be accounted for as a separate performance obligation. In that regard, ASU 2016-10 requires that an entity determine whether its promise is to transfer individual goods or services to the customer, or a combined item (or items) to which the individual goods and services are inputs. In addition, ASU 2016-10 categorizes intellectual property, or IP, into two categories: "functional" and "symbolic." Functional IP has significant standalone functionality. All other IP is considered symbolic IP. Revenue from licenses of functional IP is generally recognized at a point in time, while revenue from licenses of symbolic IP is recognized over time.

ASU 2016-10 has the same effective date and transition requirements as ASU 2014-09, as amended by ASU 2015-14. In March 2016, the FASB issued ASU No. 2016-08, Revenue from Contracts with Customers (Topic 606), Principal versus Agent Considerations (Reporting Revenue Gross versus Net), or ASU 2016-08, which clarifies the implementation guidance on principal versus agent considerations contained in ASU 2014-09 by specifying that the determination as to whether an entity that is involved in providing a good or a service to a customer is a principal or an agent is based upon whether the entity controls the good or the service before it is transferred to the customer. ASU 2016-08 has the same effective date and transition requirements as ASU 2014-09, as amended by ASU 2015-14. The adoption of ASU 2016-20 on January 1, 2018 did not have a material effect on the Company's financial position, results of operations or cash flows.

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers*, or ASU 2014-09, which provides a single, comprehensive revenue recognition model for all contracts with customers. The core principal of ASU 2014-09 is that an entity should recognize revenue when it transfers control of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. ASU 2014-09 also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. ASU 2014-09 is effective for annual periods, and interim periods within those annual periods, beginning after December 15, 2017 for public companies and December 15, 2018 for non-public companies. The Company is allowed to adopt ASU 2014-09 either (1) retrospectively to each prior reporting period presented using several practical expedients related to completed contracts and required disclosures, or (2) using a modified retrospective approach, with the cumulative effect of initially applying ASU 2014-09 recognized as an adjustment to the opening balance of retained earnings of the annual reporting period that includes the date of initial application, including disclosure of the effect of using this method of adoption on the financial statement line items. Because the Company has no contracts with customers, the adoption of ASU 2014-09 on January 1, 2018 did not have a material effect on the Company's financial position, results of operations or cash flows.

In November 2016, the Financial Accounting Standards Board, or FASB issued ASU No. 2016-18, *Statement of Cash Flows (Topic 230)*, *Restricted Cash* (a consensus of the Emerging Issues Task Force), or ASU 2016-18, which changes the presentation of the cash flow statement to include amounts generally described as restricted cash or restricted cash equivalents, together with cash and cash equivalents, when reconciling the beginning-of-period and end-of-period amounts shown on the statement of cash flows. ASU 2016-18 also requires additional disclosures concerning the nature of the restrictions on cash and cash equivalents and a reconciliation between amounts of cash, cash equivalents and restricted cash on the balance sheet and statement of cash flows for each period presented. ASU 2016-18 was applied retrospectively to all periods presented and is effective for public business entities for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. Early adoption is permitted, including adoption in an interim period. Prior to adoption, the Company presented changes in restricted cash as an operating activity in the statement of cash flows. Upon adoption of ASU 2016-18 on January 1, 2018, such changes are now reflected in the beginning and ending balances of cash, cash equivalents and restricted cash for all periods presented. Cash flows used in operating

### MEIRAGTX LIMITED AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

activities decreased by \$441,049 and increased by \$321,468 for the years ended December 31, 2016 and 2017, respectively, and \$0 for the three month period ended March 31, 2017.

As of December 31, 2016, the Company adopted Accounting Standards Update, or ASU, 2014-15 *Presentation of Financial Statements – Going Concern (Subtopic 205-40)*, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*, or ASU 2014-15, which is effective for annual periods ending after December 15, 2016, and interim periods within annual periods beginning after December 15, 2016. ASU 2014-15 codifies, for the first time within GAAP, management's responsibility to evaluate whether there is substantial doubt about the Company's ability to continue as a going concern and to provide related footnote disclosures in connection with preparing financial statements for each annual and interim reporting period. Substantial doubt about the Company's ability to continue as a going concern exists when there are conditions or events, considered in the aggregate, that are known and reasonably knowable at the date that the financial statements are issued, that indicate that the Company will be unable to meet its obligations as they become due within one year after that date. In that case, ASU 2014-15 requires the Company to disclose the nature of those conditions or events when they are present, management's plans to mitigate those conditions or events and whether or not such plans alleviated the substantial doubt. Management's evaluation as of the date of issuance of the consolidated financial statements for the year ended December 31, 2017 and three month period ended March 31, 2018 indicate that the Company will not be able to meet its obligations as they become due within one year of the financial statement issuance date (See Note 1).

As of January 1, 2016, the Company adopted ASU No. 2016-09, *Improvements to Employee Share-Based Payment Accounting*, or ASU 2016-09, which amends Accounting Standards Codification, or ASC, *Topic 718*, *Compensation – Stock Compensation*, and is effective for fiscal years beginning after December 15, 2016, and interim periods within those fiscal years for public companies and December 15, 2017 for non-public companies. The Company early adopted ASU 2016-09 during the year ended December 31, 2016. ASU 2016-09 simplifies several aspects of the accounting for share-based payment transactions, including the accounting for forfeitures, income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. The amendments will be applied prospectively. Upon adoption, the Company is accounting for forfeitures as they occur rather than estimate a forfeiture rate. As the Company did not issue any stock options prior to the date of adoption and the Company did not record any forfeitures related to restricted share grants to executives in 2015 as there was no expectation that they would leave the Company prior to the vesting dates, a cumulative-effect adjustment was not necessary. In periods subsequent to adoption, a higher expense is recognized earlier during the respective vesting periods of stock-based awards that are not forfeited. The income tax amendments within ASU 2016-09 will have no impact on its results of operations or cash flows because it is in a net operating loss position with a full valuation allowance.

#### Recent Accounting Pronouncements Not Yet Adopted

In December 2016, the FASB issued ASU No. 2016-20, *Technical Corrections and Improvements to Topic 606, Revenue from Contracts with Customers*, or ASU 2016-20, that allows entities not to disclose variable consideration allocated to performance obligations related to either: (1) sales—or usage -based royalties on licenses of intellectual property or (2) variable consideration allocated entirely to a wholly unsatisfied performance obligation or to a wholly unsatisfied promise to transfer a distinct good or service that forms part of a single performance obligation when certain criteria are met. ASU 2016-20 also requires entities that use any of the new or previously existing optional exemptions to expand their qualitative disclosures. It also makes 12 additional technical corrections and improvements to the new revenue standard, ASU 2014-09. The amendments have the same effective date and transition requirements as ASU 2014-09. The Company does not expect the adoption of ASU 2016-20 to have a material effect on its financial position, results of operations or cash flows.

### MEIRAGTX LIMITED AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

In October 2016, the FASB issued ASU 2016-16, Income Taxes (Topic 740): *Intra-Entity Transfers of Assets Other than Inventory*, or ASU 2016-16 which requires that an entity recognize the income tax consequences of an intra-entity transfer of assets other than inventory when the transfer occurs. The guidance must be applied using the modified retrospective basis. The Company does not expect the provisions of ASU 2016-16 to have a material impact on its current financial statements. This update will be effective for the Company at the beginning of fiscal 2019.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*, or ASU 2016-02, which requires lessees to recognize the following for all leases (with the exception of short-term leases) at the commencement date: a lease liability, which is a lessee's obligation to make lease payments arising from a lease, measured on a discounted basis; and a right-of-use asset, which is an asset that represents the lessee's right to use, or control the use of, a specified asset for the lease term. The revised guidance must be applied on a modified retrospective transition approach for leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements. The revised guidance is effective for the Company at the beginning of Fiscal 2019. The Company is currently evaluating the impact this ASU will have on its consolidated financial statements.

#### 3. Asset Acquisition:

Effective January 1, 2016, the Company and BRI-Alzan, Inc. ("BRI-Alzan"), a Delaware corporation, entered into an Agreement and Plan of Merger ("Agreement") to acquire all of the outstanding shares of BRI-Alzan from the shareholders of BRI-Alzan. Prior to entering into the Agreement, BRI-Alzan was an inactive entity that held a worldwide license agreement, dated May 1, 2013, with Brandeis University ("Brandeis") to develop certain pre-clinical technology for the treatment of ALS, but had not yet begun any development activities. In connection with the Agreement, the Company issued 300,000 Ordinary Shares and is required to make certain development milestone payments and royalty payments on the net sales of a product containing the technology in the event that the Company is able to achieve those milestones and develop a marketable product (see Note 15).

The Company determined this transaction represented an asset acquisition as no processes were acquired as defined by ASC 805. The asset acquisition of in process research and development was recorded at a fair value of \$597,300 as of January 1, 2016. The acquired in process research and development was immediately charged to research and development expense in the statement of operations and comprehensive loss as of the acquisition date since the Company determined that there was no additional alternative use of these assets. Additionally, under ASC 805, the Company determined that as of the acquisition date and as of December 31, 2016, December 31, 2017 and March 31, 2018, the contingent milestone payments in the aggregate amount of \$4,500,000, and royalty payments have not been resolved and therefore have not been recorded as liability.

#### 4. Prepaid Expenses:

Prepaid expenses for the periods presented consist of the following:

	December 31, 2016	December 31, 2017	March 31, 2018
Research and Development	\$ 418,483	\$ 624,348	\$ 630,196
Professional Fees	_	_	1,076,276
Clinical Trial Costs	204,028	497,869	503,941
Clinical Trial Materials	_	341,775	352,734
Dues and License Fees	49,487	145,594	106,012
Insurance	144,525	163,284	118,936
Rent	214,764	27,778	_
Other	180,896	160,595	28,318
	\$ 1,212,183	\$ 1,961,243	\$ 2,816,413

#### 5. Property & Equipment, net:

Property and equipment, net for the periods presented consist of the following:

	December 31, 2016	December 31, 2017	March 31, 2018
Leasehold Improvements	\$ 2,203,282	\$ 10,873,895	\$ 11,284,844
Manufacturing Equipment	_	2,477,637	2,894,101
Laboratory Equipment	662,443	993,409	1,017,169
Office Equipment	100,350	276,100	282,172
Asset Retirement Obligation	205,659	153,133	158,044
Furniture & Fixtures	78,708	93,786	96,395
	3,250,442	14,867,960	15,732,725
Less: Accumulated depreciation	(233,917)	(612,231)	(1,089,634)
	\$ 3,016,525	\$ 14,255,729	\$ 14,643,091

In connection with an operating lease, the Company estimated that it had an asset retirement obligation, which is included in other liabilities on the consolidated balance sheets, at the end of the initial five-year lease term in the amount of \$306,400. The Company discounted the asset retirement obligation using an 8% discount rate and recorded an asset retirement obligation in the amount of \$205,659 as of December 31, 2016, which is included in leasehold improvements and was being depreciated over the five-year term of the lease (see Note 15). As of December 31, 2017, the Company determined that it is probable that it will exercise the additional five-year option provided for in the operating lease. Therefore, the company revalued the asset retirement obligation over the remaining eight-year lease term and recorded a reduction in the asset retirement obligation of \$75,011 recorded in leasehold improvements. The remaining net book value is being depreciated over the remaining eight-year lease term.

Capitalized leases in the amount of \$17,817, \$95,880 and \$114,924 are included in office equipment at December 31, 2016 and 2017 and March 31, 2018, respectively, and accumulated depreciation of \$6,928, \$34,552 and \$46,390 at December 31, 2016 and 2017 and March 31, 2018, respectively.

Depreciation expense was \$243,081 and \$679,177 for the years ended December 31, 2016 and 2017, respectively and \$179,878 and \$458,836 for the three months ended March 31, 2017 and 2018, respectively.

#### 6. Restricted Cash:

The Company is required to maintain stand-by letters of credit as security deposits under each of the ARE-East River Science Park LLC ("ARE") leases (see Note 14). The fair value of each letter of credit approximates its contract value. In each case, the Company's bank requires the Company to maintain restricted cash balances to serve as collateral for the letter of credit issued to the landlord by the bank. In connection with an amendment to one of the ARE leases in November 2017, the letter of credit in the amount of \$321,978 and the related restricted cash balance were released in December 2017. As of December 31, 2016 and 2017 and March 31, 2018, the restricted cash balances for the ARE leases were invested in a commercial money market account.

The restricted cash balance for the other ARE lease remains at \$123,376 through the end of the lease term in December 2021, plus three months.

The Company had \$444,844, \$123,376 and \$123,376 of restricted cash included in long-term assets as of December 31, 2016 and 2017 and March 31, 2018, respectively and is measured using level 1 inputs.

Upon the retrospective adoption of ASU 2016-18 on January 1, 2018, as discussed in Footnote 2, restricted cash is now reflected in the beginning and ending balance of cash, cash equivalents and restricted cash for all periods presented in the Consolidated Statements of Cash Flows. As a result of this retrospective adoption, cash flows used in operating activities decreased by \$441,049 and increased by \$321,468 for the years ended December 31, 2016 and 2017, and \$0 for the three month period ended March 31, 2017, respectively, resulting in revised net cash used in operating activities of \$14,367,952 and \$18,055,386 for the years ended December 31, 2016 and 2017, respectively, presented in the Consolidated Statements of Cash Flows.

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the balance sheet that sum to the total of the same such amounts shown in the statement of cash flows:

	December 31, 2016	December 31, 2017	March 31, 2018
Cash and cash equivalents	\$ 17,476,641	\$ 8,548,638	\$ 32,356,851
Restricted cash	444,844	123,376	123,376
Total cash, cash equivalents and restricted cash			
shown in the statement of cash flows	\$ 17,921,485	\$ 8,672,014	\$ 32,480,227

#### 7. Accrued Expenses:

Accrued expenses for the periods presented were comprised of the following:

	December 31, 2016	December 31, 2017	March 31, 2018
Clinical Trial Costs	\$ 664,149	\$ 4,859,410	\$ 4,243,611
Compensation and Benefits	1,418,958	2,386,903	390,896
Consulting	1,158,915	1,220,477	672,947
Rent	242,937	387,267	106,381
Professional Fees	323,102	231,923	910,081
Interest	_	33,437	25,500
Other	210,042	213,527	307,841
	\$ 4,018,103	\$ 9,332,944	\$ 6,657,257

#### 8. Capitalized Leases:

In 2015, the Company acquired certain office equipment in the amount of \$17,817 under a 3-year lease arrangement. The Company determined that the lease should be capitalized since it contained a bargain purchase option for the equipment at the end of the lease term. Total payments under the capital lease amounted to \$20,502 and had an interest rate of 9.35%.

In 2017, the Company acquired additional office equipment in the amount of \$78,063 under a 3-year lease arrangement. The Company determined that the lease should be capitalized since it contained a bargain purchase option for the equipment at the end of the lease term. Total payments under the capital lease amounted to \$86,145 and had an interest rate of 6.90%.

The following is a schedule, by year, of future minimum lease payments under the capital leases together with the present value of the net minimum lease payments as of December 31, 2016 and 2017 and March 31, 2018:

	December 31, 2016	December 31, 2017	March 31, 2018
2018	\$ 6,834	\$ 34,410	\$ 25,523
2019	5,695	28,715	28,715
2020	_	7,179	7,179
Total minimum lease payments	12,529	70,304	61,417
Less: amount representing interest	(1,056)	(5,156)	(4,047)
Present value of net minimum lease			
payments	11,473	65,148	57,370
Less: current portion	(6,015)	(30,850)	(28,715)
Obligations under capital lease, less			
current portion	\$ 5,458	\$ 34,298	\$ 28,655

#### 9. Notes Payable

On October 26, 2017, in connection with an amendment to an existing lease, the Company issued a promissory note in the amount of \$1,442,009 to ARE, the landlord and also a related party (see Note 15). The note bears interest at the rate of 5% per annum and is due on December 31, 2018. However, if the Company has sufficient liquidity, as defined in the note, then the note, including accrued interest, will become due and payable at that time. If the Company does not have sufficient liquidity, which is defined as Company's cash, cash equivalents and liquid short-term investments of at least an investment grade are at least twenty times greater than the promissory note plus accrued interest, the Company has the right to repay the note on the due date in either cash or Preferred Shares of the Company. In March 2018, the Company repaid the note in full in cash. The Company recorded interest expense in the consolidated statement of operations and comprehensive loss in connection with the note in the amount of \$13,037 and \$17,386 for the year ended December 31, 2017 and for the three months ended March 31, 2018, respectively.

#### 10. Share-Based Compensation

#### 2016 Equity Incentive Plan

The Company's 2016 Equity Incentive Plan (the "Plan"), was adopted by the Company's board of directors and shareholders. Under the Plan, the Company has granted share options to selected officers,

### MEIRAGTX LIMITED AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

employees and non-employee consultants. The Company's board of directors administer the Plan. Options granted under the Plan have a maximum contractual term of ten years. Options granted generally vest 25% on the first anniversary date of grant and the balance ratably over the next 36 months.

A summary of the Company's share option activity related to employees, non-employee members of the board of directors and non-employee consultants as of and for the years ended December 31, 2016 and 2017 and the three months ended March 31, 2018 is as follows:

	Number of Options	Averag	eighted- ge Exercise Price	Aggrega Instrinsic	
Outstanding at December 31, 2015	_	\$		\$	—
Granted	1,295,000		1.99		
Exercised	_		_		
Expired	_		_		
Forfeited					
Outstanding at December 31, 2016	1,295,000	\$	1.99	\$	_
Granted Exercised	2,375,000		0.96		
Expired	(5,000)		(1.95)		
Forfeited	(22,000)		(1.99)		
Outstanding at December 31, 2017	3,643,000	\$	1.32	\$ 1,420	650
Granted	2,622,500	ψ	1.45	φ 1,420	,050
Exercised	2,022,500				
Expired	_		_		
Forfeited	_		_		
Outstanding at March 31, 2018	6,265,500	\$	1.37	\$ 1,867	,400
Weighted average remaining contractual life of options outstanding as of December 31, 2016 (yrs)	9.19				
Weighted average remaining contractual life of options outstanding as of December 31, 2017 (yrs)	9.09				
Weighted average remaining contractual life of options outstanding as of March 31, 2018 (yrs)	9.22				
Options exercisable at December 31, 2016	125,000	\$	1.99	\$	_
Options exercisable at December 31, 2017	723,398	\$	1.99	\$	_
Options exercisable at March 31, 2018	912,854	\$	1.98	\$	_
Weighted average remaining contractual life of options exercisable as of December 31, 2016 (yrs)	9.24				
Weighted average remaining contractual life of options exercisable as of December 31, 2017 (yrs)	8.21				
Weighted average remaining contractual life of options exercisable as of March 31, 2018 (yrs)	8.07				

### MEIRAGTX LIMITED AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

The total fair value of options vested during the years ended December 31, 2016 and 2017 and the three months ended March 31, 2018, was \$180,723, \$898,699 and \$309,147, respectively.

During the years ended December 31, 2016 and 2017 and the three months ended March 31, 2018, the Company granted 915,000, 1,020,000 and 2,070,000 share options, respectively, to employees and non-employee members of the board of directors. The grant date fair values of the stock options granted to those groups were estimated using the Black-Scholes option valuation model with the following ranges of assumptions (see Note 2):

			For the Three Month
	For the Year Ended December 31,		Period Ended March 31,
	2016	2017	2018
Risk-free interest rate	1.38% - 1.55%	2.28%	2.32% - 2.40%
Expected volatility	90%	90%	90%
Expected dividend yield	0%	0%	0%
Expected life of employee and Board of Directors' options (in years)	5.0 - 6.1	5.5 - 6.1	5.5 - 6.1

As of December 31, 2016 and 2017 and March 31, 2018, the total compensation expense relating to unvested options granted to employees and non-employee members of the board of directors that had not yet been recognized was \$800,976, \$987,413 and \$2,912,830, respectively which is expected to be realized over a period of 3.17, 3.42 and 3.78 years, respectively. The Company will issue shares upon exercise of options from Ordinary Shares reserved.

During the years ended December 31, 2016 and 2017 and the three months ended March 31, 2018, the Company granted 380,000, 1,355,000 and 552,500 share options, respectively to non-employee consultants. In accordance with ASC 505-50, on December 31, 2016 and 2017 and March 31, 2018, the Company remeasured the fair value, of all unvested outstanding options that had been granted to non-employee consultants using the Black-Scholes option valuation model with the following ranges of assumptions:

	F 4 W		For the Three Month Period Ended March 31.
	2016	For the Year Ended December 31, 2016 2017	
Risk-free interest rate	2.45%	2.36% - 2.39%	2.76% - 2.81%
Expected volatility	90%	90%	90%
Expected dividend yield	0%	0%	0%
Expected life of non-employee options (in years)	9.2 - 10.0	8.2 - 9.7	7.9 - 9.8

As of December 31, 2016 and 2017 and March 31, 2018, the total compensation expense relating to unvested options granted to non-employee consultants that had not yet been recognized was \$456,707, \$1,629,019 and \$2,130,007, respectively, which is expected to be realized over a period of 3.17, 3.72 and 3.78 years, respectively. The Company will issue shares upon exercise of options from Ordinary Shares reserved.

The weighted average grant date fair value of options granted to employees, non-employee members of the board of directors for their Board service and non-employee consultants during the years ended December 31, 2016 and 2017 and the three months ended March 31, 2018 was \$1.51, \$0.80 and \$1.12, respectively.

#### **Restricted Shares**

In 2015, in connection with certain service and consulting agreements, certain employees and a consultant were awarded an aggregate of 3,367,710 restricted Ordinary Shares and 750 restricted B ordinary

shares, which restricted B ordinary shares were converted into restricted Ordinary Shares, of the Company. Such shares are subject to forfeiture over a three-year service period. The shares were valued at \$1.99 and \$2.00 per share and is included in loss from operations over the requisite service period.

A summary of the restricted Ordinary Shares is as follows:

	Ordinary Shares	\$ Value
Total restricted Ordinary Shares Issued	3,368,460	\$6,730,290
Non-vested at December 31, 2015	2,590,478	5,175,857
Vested during 2016	1,090,049	2,155,666
Non-vested at December 31, 2016	1,500,429	3,020,191
Vested during 2017	1,089,380	2,154,330
Non-vested at December 31, 2017	411,049	865,861
Vested during the three-month period ended March 31, 2018	266,403	532,364
Non-vested at March 31, 2018	144,646	\$ 333,497

During the years ended December 31, 2016 and 2017 and the three months ended March 31, 2018 the Company recognized total share-based compensation expense in the accompanying statements of operations and comprehensive loss as follows:

	December 31, 2016	December 31, 2017	March 31, 2018
Research and development	\$ 1,995,594	\$ 2,374,899	\$ 842,962
General and administrative	811,367	584,832	3,432,774
Total share based compensation	2,806,961	\$ 2,959,731	\$ 4,275,736

The Company does not expect to realize any tax benefits from its share option activity or the recognition of share-based compensation expense because the Company currently has net operating losses and has a full valuation allowance against its deferred tax assets. Accordingly, no amounts related to excess tax benefits have been reported in cash flows from operations or cash flows from financing activities for the years ended December 31, 2016 and 2017 and the three months ended March 31, 2018.

#### 11. Convertible Preferred C Shares and Shareholders' Deficit:

#### Registration Rights Related to Ordinary Shares and Preferred Shares

Holders of Preferred Shares who hold not less than 3% of the Company's fully diluted shares and certain other shareholders have piggyback registration rights with respect to the Company's registration of its Ordinary Shares following an initial public offering, subject to certain exceptions.

#### Drag-Along Rights Related to Ordinary and Preferred Shares

Pursuant to the Company's articles of association, if the holders of at least 50% of the voting power of the Company wish to sell their Ordinary Shares and/or Preferred Shares, then such holders have the right to require all other holders to accept the offer made to the them and sell their Ordinary Shares and/or Preferred Shares on the same terms, subject to certain exceptions with respect to the Company's registration of its Ordinary Shares.

### MEIRAGTX LIMITED AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

#### **Ordinary Shares**

Voting Rights

Each share is entitled to one vote.

Redemption

The shares are not redeemable.

**Transfers** 

Transfers to an affiliate or member, as defined, are permitted. Otherwise, the Ordinary Shares may not be transferred without approval from the Company's board of directors. If the transfer is approved, the Company has the right to purchase any or all of the Ordinary Shares on the same terms and conditions. If the Company does not exercise its right to purchase the Ordinary Shares, then the other shareholders have the right to purchase the Ordinary Shares on a pro-rata basis.

Tag-Along Rights

Pursuant to the Company's articles of association, if Kadmon holds more than 15% of the fully diluted share capital and proposes to transfer more than 25% of the aggregate number of Ordinary Shares held by Kadmon and its affiliates to a third-party purchaser, before making such a transfer Kadmon must offer to all of the MeiraGTx UK II founders the right to purchase the same proportion of the Ordinary Shares held by each MeiraGTx UK II founder on the proportion of shares being sold by Kadmon and its affiliates, subject to certain exceptions with respect to the Company's registration of its Ordinary Shares.

Right to Appointment of Board Member

Pursuant to the Company's shareholders' agreement, as long as Kadmon's ownership percentage of the Company is at least 10%, Kadmon has the right to appoint a board member to the Company's board of directors. This right in the shareholders' agreement terminates upon an initial public offering.

Issuances

2016

On January 1, 2016, the Company issued 300,000 Ordinary Shares in connection with the BRI-Alzan acquisition described in Note 3.

On April 5, 2016, the Company issued 4,017,048 Ordinary Shares in connection with the acquisition of the remaining 40% of MeiraGTx UK II described in Note 2.

On April 7, 2016, the Company issued 46,300 Ordinary Shares in connection with a consulting agreement.

On July 7, 2016, all of the 10,000 B ordinary shares outstanding were converted into 10,000 Ordinary Shares.

### MEIRAGTX LIMITED AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

2017

On July 31, 2017, the Company issued 5,000 Ordinary Shares in connection with the exercise of an option.

On August 16, 2017, the Company issued 25,000 Ordinary Shares in connection with a research agreement.

2018

On March 1, 2018, a funding milestone was met under the employment agreements for certain senior management. Accordingly, the employees were issued an aggregate of 2,135,182 fully vested Ordinary Shares, which represented 3% of the fully-diluted outstanding shares of the Company as of such date. The shares were recorded as share-based compensation in the amount of \$3,096,104. Additionally, under the terms of the employment agreements, the Company was required to pay the income taxes on those shares on behalf of the executives. Total compensation expense in connection with the issuance of these Ordinary Shares, in the amount of \$6,154,608, was recorded as general and administrative expense during the three-month period ended March 31, 2018.

#### Convertible Preferred C Shares

#### Redemption

The Preferred Shares are not redeemable. However, in the event of a Sale (as defined in the Company's Articles of Association), which would include a change of control that is outside of the Company's control, the Preferred Shares are entitled to receive a payment which is equal to their liquidation value. The feature is being accounted for as a redemption under ASC 480.

The Company is accounting for its Preferred Shares under the requirements of ASC 480 which establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. The carrying value of the Preferred Shares is presented in as temporary equity and is increased by periodic accretions so that the carrying amount will equal the redemption amount at the estimated date that the Preferred Shares will be converted into Ordinary Shares. These increases are affected through charges against additional paid-in capital, to the extent it is available, or accumulated deficit. For all Preferred Shares issuances, the difference between the amount invested by the holders of the Preferred Shares, net of issuance costs, and the initial fair value of warrants issued in connection with the Preferred Shares (if applicable) and the liquidation value of the Preferred Shares, is recorded as accretion over the estimated life of the Preferred Shares. The accretion is added to net loss to arrive at the net loss available to Ordinary Shareholders in the calculation of loss per Ordinary Share.

#### Liquidation Preference

The Preferred Shares contain a liquidation preference whereby on a return of assets on liquidation or capital reduction or otherwise, the surplus assets and retained profits of the Company available for distribution among the holders of Shares shall be applied:

- first in paying to the holders of Preferred Shares a sum equal to \$2.70; and
- second, the balance of such assets (if any) shall be distributed amongst the holders of Ordinary Shares pro rata to the number of shares held by each of them respectively.

### MEIRAGTX LIMITED AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

In September 2017, the shareholders amended the Company's articles of incorporation to reduce the liquidation value of the Preferred Shares from \$5.40 to \$2.70. Concurrently, the board of directors approved a dividend of 6,149,326 Preferred Shares to the existing holders of 6,149,326 Preferred Shares that had previously been purchased from the Company at a liquidation value of \$5.40 per share. The Company has accounted for this amendment as an extinguishment. The new Preferred Shares issued in connection with the extinguishment were recorded at fair value. The fair value of the newly issued Preferred Shares issued in connection with the extinguishment was determined based upon recent sales of the Company's Preferred Shares to third parties on or about the time of the extinguishment. The extinguishment and concurrent dividend resulted in \$0.1 million of loss being added to loss available to ordinary shareholders for earning per share purposes. (see Note 12).

Conversion

The Preferred Shares may be converted by the holder into Ordinary Shares, on a one to one basis, at any time, subject to adjustment for share splits and share dividends. The Preferred Shares shall automatically be converted and reclassified as Ordinary Shares with effect from and immediately prior to the completion of a Qualified IPO.

Dividends

There are no dividends on the Preferred Shares.

Voting Rights

Each Preferred Share is entitled to one vote.

**Transfers** 

Transfers to an affiliate or member, as defined, are permitted. Otherwise, the Preferred Shares may not be transferred without approval from the Company's board of directors. If the transfer is approved, the Company has the right to purchase any or all of the Preferred Shares on the same terms and conditions. If the Company does not exercise its right to purchase the Preferred Shares, then the other Preferred Shareholders has the right to purchase the Preferred Shares on a pro-rata basis.

**Pre-Emptive Rights** 

The holders of the Preferred Shares have the right to participate in any new offering of equity shares in the same proportion as their holdings prior to the new offering.

Tag-Along Rights

If one or more of the holders proposes to transfer 15% or more of all shares issued by the Company, the transferee of the shares must offer to purchase from each holder of the Preferred Shares such proportion of the number of each class of shares registered in their name as is equal to the proportion which the shares that the transferor are proposing to transfer to the transferee.

Right to Appointment of Board Member

As long as Perceptive Life Sciences Master Fund, Ltd., holds not less than 50% of the Preferred Shares it owned on September 18, 2017 and April 12, 2018, it shall have the right to appoint a board member to the Company's board of directors, which it did on October 19, 2017. This right in the shareholders' agreement terminates upon an initial public offering.

# MEIRAGTX LIMITED AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

**Issuances** 

2016

During the year ended December 31, 2016, the Company issued 3,877,827 Preferred Shares at an offering price of \$5.40 per share for proceeds of \$20,770,031, net of issuance costs of \$177,623. The net proceeds of the offering are being used for working capital, research and development and general corporate purposes.

In April 2016, the Company issued 230,000 Preferred Shares in the amount of \$1,242,000 as partial payment for amounts due to Affiliate.

On December 20, 2016, the Company issued 59,259 Preferred Shares in connection with a license agreement described in Note 15.

2017

During the year ended December 31, 2017, the Company issued 37,800 Preferred Shares at an offering price of \$5.40 per share and 6,203,459 Preferred Shares at an offering price of \$2.70 per share for gross proceeds of \$16,854,656, excluding offering costs of \$98,804. The net proceeds of the offering are being used for working capital, research and development and general corporate purposes.

On November 2, 2017, a note payable to a related party in the amount of \$2,500,000 was converted at the rate of \$2.70 per share, into 925,926 Preferred Shares (see Note 15).

2018

During the three-month period ended March 31, 2018, the Company issued 16,348,917 Preferred Shares at an offering price of \$2.70 per share for gross proceeds of \$44,142,076, excluding offering costs of \$290,475.

Also, during the three-month period ended March 31, 2018, the Company issued 501,886 Preferred Shares in lieu of cash payment of an aggregate amount \$1,355,097 to certain vendors.

On March 15, 2018, the Company issued 51,852 Preferred Shares in connection with a license agreement.

The net proceeds of the offering are being used for working capital, research and development and general corporate purposes.

#### Warrants

In connection with the issuance of 2,777,778 Preferred Shares on September 21, 2017, at an offering price of \$2.70 per share, the Company issued warrants to purchase 2,700,000 Preferred Shares at an exercise price of \$2.70 per share. The warrants expire on the first of the following to occur:

- (i) an Asset Sale;
- (ii) a Oualified IPO:
- (iii) a Share Sale;
- (iv) the winding up of the Company; or
- (v) On the third anniversary of the date of issuance

# MEIRAGTX LIMITED AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

The Black-Sholes value of the warrants in the amount of \$1,660,500 was accounted for as a warrant liability and a discount to the Preferred Shares at the time of issuance and is being accreted over the expected term of the Preferred Shares (see Note 2).

In connection with the conversion of a \$2,500,000 note payable into 925,926 Preferred Shares on November 2, 2017, as an inducement to convert, the Company issued warrants to purchase 900,000 Preferred Shares to the note holder under the same terms and conditions as the warrants issued on September 21, 2017 (see Note 15).

The Black-Scholes value of the warrants in the amount of \$553,500 was recorded as a warrant liability and charged to convertible note inducement expense within the statement operations and comprehensive loss at the time of issuance.

Both of the warrants were revalued under the Black-Scholes valuation model at December 31, 2017 and March 31, 2018, which resulted in an increase of the warrant liability in the amount of \$465,633 and a decrease of the warrant liability in the amount of \$669,408, respectively, which was charged to change in fair value of warrant liability within the statement of operations and comprehensive loss.

The warrant liability at December 31, 2017 and March 31, 2018 was \$2,679,633 and \$2,010,225, respectively.

# MEIRAGTX LIMITED AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

## 12. Net Loss per Share

The Company computes net loss per share in accordance with ASC 260-10, *Earnings per Share* (see Note 2,).

	For the Year Ended December 31,	
	<u>2016</u>	<u>2017</u>
Net loss attributable to MeiraGTx ordinary shareholders - basic and diluted	\$ (19,486,393)	\$ (31,044,535)
Accretion of Preferred Shares financing costs	(85,425)	(191,963)
Accretion of warrant		(615,000)
Adjusted net loss attributable to MeiraGTx ordinary shareholders - basic and diluted	\$ (19,571,818)	\$ (31,851,498)
Weighted-average ordinary shares outstanding:		
Basic and Diluted	31,098,591	33,269,157
Net loss per share:		
Basic and Diluted	\$ (0.63)	\$ (0.96)
		e Month Period March 31, 2018
Net loss attributable to MeiraGTx ordinary shareholders - basic and diluted	Ended I	March 31,
Net loss attributable to MeiraGTx ordinary shareholders - basic and diluted Accretion of Preferred Shares financing costs	Ended I <u>2017</u>	March 31, 2018
, and the state of	Ended I 2017 \$ (6,820,385)	March 31, 2018 \$(16,403,353)
Accretion of Preferred Shares financing costs	Ended I 2017 \$ (6,820,385)	March 31, 2018 \$(16,403,353) (94,445)
Accretion of Preferred Shares financing costs Accretion of warrant	Ended M 2017 \$ (6,820,385) (22,761) —	March 31, 2018 \$(16,403,353) (94,445) (570,273)
Accretion of Preferred Shares financing costs Accretion of warrant Adjusted net loss attributable to MeiraGTx ordinary shareholders - basic and diluted	Ended M 2017 \$ (6,820,385) (22,761) —	March 31, 2018 \$(16,403,353) (94,445) (570,273)
Accretion of Preferred Shares financing costs Accretion of warrant Adjusted net loss attributable to MeiraGTx ordinary shareholders - basic and diluted Weighted-average ordinary shares outstanding:	2017 \$ (6,820,385) (22,761) ————————————————————————————————————	March 31, 2018 \$(16,403,353) (94,445) (570,273) \$(17,068,071)

The following securities are considered to be Ordinary Share equivalents, but were not included in the computation of diluted net loss per Ordinary Share because to do so would have been anti-dilutive:

	December 31, 2016	December 31, 2017
Preferred Shares	6,111,256	19,428,037
A restricted ordinary shares subject to forfeiture	1,489,333	411,049
Stock options	1,295,000	3,643,000
Warrants	<del>_</del>	3,600,000
	8,895,589	27,082,086
	<u> </u>	
	March 31, 2017	March 31, 2018
Preferred Shares	6,149,326	36,330,692
A restricted ordinary shares subject to forfeiture	1,222,930	144,646
Stock options	1,720,000	6,265,500
Warrants		3,600,000
	9,092,256	46,340,838

# MEIRAGTX LIMITED AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

## 13. Pro Forma Net Loss Per Share (unaudited)

The following table sets forth the computation of the Company's unaudited pro forma basic and diluted net loss per share:

	Year Ended December 31,2017	Three-Month Period Ended March 31, 2018
Numerator:		
Adjusted net loss attributable to MeiraGTx Limited ordinary shareholders	\$ (31,851,498)	\$(17,068,071)
Accretion on convertible preferred C shares	806,963	664,718
Change in fair value of warrant liability	465,633	(669,408)
Acceleration of vesting on restricted shares	(175,983)	_
Pro forma adjusted net loss attributable to MeiraGTx Limited ordinary shareholders	\$ (30,754,885)	\$(17,072,761)
Denominator:		
Weighted-average number of ordinary shares outstanding	33,269,157	34,647,368
Pro forma adjustment to reflect the automatic conversion of convertible preferred C shares upon the		
closing of the proposed initial public offering	36,330,392	36,330,392
Pro forma adjustment to reflect to exercise of the warrants prior to the closing of the proposed initial		
public offering	3,600,000	3,600,000
Acceleration of vesting on restricted shares	89,398	89,398
Pro forma weighted-average number of ordinary shares outstanding	73,288,947	74,667,158

#### 14. Income Taxes:

Since the Company has recurring losses and a valuation allowance against deferred tax assets, there is no tax expense (benefit) for the years ended December 31, 2016 or 2017 and for the three month periods ended March 31, 2017 or 2018.

Each Company files separate tax returns in its respective tax jurisdictions.

As of December 31, 2017, the Company had federal and state net operating loss ("NOL") carryforwards in the United States of approximately \$7,820,000 and \$7,779,000, respectively, and in the United Kingdom of approximately \$39,971,000, which are available to reduce future taxable income. The U.S. federal and state NOL carry forwards will begin to expire in 2035 and the U.K. NOL will continue indefinitely under current UK legislation. Also, as of December 31, 2017, the Company had research and development credits in the U.S. in the amount of \$697,000. The NOL carry forwards are subject to review and possible adjustment by the U.S., U.K. and state tax authorities. NOL carry forwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant shareholders, as defined under Sections 382 Internal Revenue Code, as well as CTA 2010 Part 14 under the UK tax rules. This could limit the amount of NOLs that the Company can utilize annually to offset future taxable income or tax liabilities. As of December 31, 2017, the Company has not performed such an analysis. Subsequent ownership changes and proposed future changes to the UK (or US) tax rules in respect of the utilization of losses carried forward may further affect the limitation in future years. Additionally, the Company has not undertaken a study on the completeness of the U.S. research and development credit. As such, the U.S. research and development credits may change.

# MEIRAGTX LIMITED AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

The Company's pre tax earnings from the United Kingdom and United States locations are as follows:

	December 31, 2016	December 31, 2017
United Kingdom	\$ (17,285,861)	\$ (26,458,625)
United States	(2,506,415)	(4,585,910)
	\$ (19,792,276)	\$ (31,044,535)

The Company is subject to the corporate tax rate in the U.K. as a Limited U.K. corporation.

The following table summarizes a reconciliation of income tax benefit compared with the amounts at the U.K. statutory income tax rate:

	December 31, 2016		December 31	, 2017
Statutory rate	(3,958,455)	3,958,455) 20.00%		19.25%
U.K. R&D credit		0.00%	654,648	-2.11%
Permanent differences—other	680,255	-3.44%	539,136	-1.74%
Impact of foreign exchange	_	0.00%	(152,948)	0.49%
U.S. R&D credit	(238,850)	1.21%	(363,665)	1.17%
Foreign tax rate differential	(341,603)	1.73%	(673,619)	2.17%
State and local rate, net of federal tax	(240,465)	1.21%	(446,683)	1.44%
Future UK Rate Change (17% at expected DTA turn)	582,910	-2.95%	482,351	-1.55%
Federal & State Rate Change (Jobs Act & MTA)	_	0.00%	993,998	-3.20%
Change in valuation allowance	3,516,208	-17.77%	4,942,855	-15.92%
Actual income tax benefit effective tax rate		0.00%	_	0.00%

The Expense/(Benefit) for income taxes from continuing operations consists of the following:

	December 31, 2016	December 31, 2017
Current Tax Expense/(Benefit)		
United Kingdom	_	_
United States	_	_
Total Current	_	_
Deferred Tax Expense/(Benefit)		
United Kingdom	(2,034,368)	(3,759,109)
United States	(1,481,840)	(1,183,746)
Total Deferred	(3,516,208)	(4,942,855)
Change in Valuation Allowance	3,516,208	4,942,855
Total Income Tax Expense/(Benefit)		

# MEIRAGTX LIMITED AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

## Deferred Tax Assets/(Liabilities)

	Total	December 31, 2016 UK	<u>US</u>
Deferred Tax Assets:	<u> </u>	<u> </u>	<u>00</u>
Net operating loss carryforwards	\$ 5,048,704	\$ 3,176,927	\$ 1,871,777
Other	373,805	126,232	247,573
R&D Credit	333,741		333,741
Deferred tax assets	5,756,250	3,303,159	2,453,091
Less: valuation allowance	(5,756,250)	(3,303,159)	(2,453,091)
Net deferred tax asset	\$ —	<del>\$</del> —	\$ —
	Total	<u>December 31, 2017</u> UK	US
Deferred Tax Assets:	<u>Total</u>		<u>us</u>
Deferred Tax Assets:  Net operating loss carryforwards	Total \$ 9,462,690		<u>us</u> \$ 2,552,937
		<u>UK</u>	
Net operating loss carryforwards	\$ 9,462,690	<u>uk</u> \$ 6,909,754	\$ 2,552,937
Net operating loss carryforwards Other	\$ 9,462,690 539,008	<u>uk</u> \$ 6,909,754	\$ 2,552,937 386,454
Net operating loss carryforwards Other R&D Credit	\$ 9,462,690 539,008 697,406	<u>UK</u> \$ 6,909,754 152,554 	\$ 2,552,937 386,454 697,406

ASC 740 requires a valuation allowance to reduce the deferred tax assets reported if, based on the weight of available evidence, it is more likely than not that some portion or all of the deferred tax assets will not be realized. After consideration of all the evidence, both positive and negative, the Company has recorded a full valuation allowance against its deferred tax assets at December 31, 2016 and 2017 because the Company's management has determined that is it more likely than not that these assets will not be fully realized.

Changes to the U.K. and U.S. corporation tax rates have been announced which will impact future accounting periods. In his budget of July 8, 2015, the Chancellor of the Exchequer announced a reduction in the U.K. corporation tax rate to 19% for the financial year beginning April 1, 2017 and a further reduction to 18% for the financial year beginning April 1, 2020. These changes received Royal Assent on November 18, 2015. The U.K. Finance Act 2016 provides for a further reduction in the corporation tax rate to 17% for the Financial Year beginning April 1, 2020. This change was enacted on September 15, 2016. As the Company does not expect to be able to utilize its NOL's in the U.K. prior to its financial year beginning on January 1, 2021, if at all, the deferred tax has been calculated using a tax rate of 17%.

In the United States, the corporation tax rate was reduced to 21% for the financial year beginning January 1, 2018. As these changes were enacted prior to the December 31, 2017 balance sheet date, deferred tax has been calculated accordingly in these consolidated financial statements, which represented a decrease in the prior years deferred tax assets of approximately \$994,000.

The Company will recognize interest and penalties related to uncertain tax positions in income tax expense. As of December 31, 2016 and 2017, the Company had no accrued interest or penalties related to uncertain tax positions and no amounts have been recognized in the Company's statements of operations and comprehensive loss.

# MEIRAGTX LIMITED AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

The Company files income tax returns in the United States and the United Kingdom, and various state jurisdictions. For tax years 2015, 2016 and 2017, the statute of examination is open in all jurisdictions in which the Company files income tax returns. The Company does not have any earnings, therefore no provision has been made for income taxes that would be payable against such foreign earnings.

## 15. Related Party Transactions:

### **Transition Services Agreement**

Effective April 24, 2015, the Company entered into a transition services agreement (the "TSA") with Kadmon, whereby Kadmon would provide office and laboratory facilities as well as certain other personnel support activities to the Company. Under the agreement, the Company is charged for (i) rent based upon the square footage of the office and laboratory facilities used by the Company (ii) other personnel support activities based upon the hours of the personnel providing the support activities, and (iii) and other direct costs incurred by Kadmon on behalf of the Company, plus a 7% administrative fee. The TSA may be terminated by either party by giving thirty-days' notice.

During the years ended December 31, 2016 and 2017 and the three months ended March 31, 2017 and 2018, the Company incurred the following charges in connection with the TSA and is included in loss from operations:

	Years Ended December 31,		Three Months		s Ended March 31,	
	<u>2016</u>	2017		2017		2018
Rent	\$ 794,087	\$548,229	9	123,355	\$	136,353
Personnel	189,104	39,721		18,532		6,493
Other	42,110	5,983		5,080		_
Total charges incurred	\$1,025,301	\$593,933	5	146,967	\$	142,846

During the year ended December 31, 2016 and 2017, the Company made cash payments totaling \$225,078 and \$275,941, respectively. During the three-month periods ended March 31, 2017 and 2018, the Company made cash payments totaling \$275,941 and \$997,417, respectively. Additionally, in April 2016, as partial payment of the amounts owed to Kadmon, the Company issued 230,000 Preferred Shares in the amount of \$1,242,000.

The amount due to Kadmon at December 31, 2016 and 2017 and March 31, 2018, is \$543,038, \$861,030, and \$6,493, respectively and is disclosed as Due to Kadmon on the balance sheet.

## Research Agreement

Effective October 23, 2016, the Company entered into a four-year master services agreement with UCL Consultants Limited, an entity affiliated with University College of London ("UCL"), which is a shareholder of the Company. Pursuant to the agreement, UCL Consultants Limited provides pre-clinical research and development under the direction of the Company. In connection with the agreement, the Company issued several work orders during the years ended December 31, 2016 and 2017 in the aggregate amounts of £1,161,149 and £241,053, respectively, or approximately \$1,574,000 and \$311,000, based upon the average exchange rates during the years ended December 31, 2016 and 2017, respectively. Either party may terminate the agreement by giving 30 days written notice. Total research and development expenses under this agreement for the years ended December 31, 2016 and 2017 and the three months ended March 31, 2017 and 2018 was approximately \$278,000 and \$538,000, and \$108,000 and \$189,000, respectively. Future obligations, under the agreement equal £927,823, or approximately \$1,301,921 through October 2020.

# MEIRAGTX LIMITED AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

The amount due to UCL under the master services agreement at December 31, 2016 and 2017 and March 31, 2018, is \$251,754, \$775,315 and \$377,145, respectively and is included in accounts payable and accrued expenses on the balance sheet.

### **Manufacturing Agreement**

Effective September 1, 2016, the Company entered into a manufacturing and drug supply agreement with UCL. Pursuant to the agreement, UCL will manufacture materials for the Company's clinical trials under the direction of the Company. Either party may terminate the agreement by giving 30 days written notice. The agreement was terminated in January 2018. Total research and development expenses under this agreement for the years ended December 31, 2016 and 2017 and the three months ended March 31, 2017 and 2018, was approximately \$456,106 and \$1,904,352, and \$563,024 and \$0, respectively.

The amount due to UCL under the manufacturing and drug supply agreement at December 31, 2016 and 2017 and March 31, 2018, is \$412,395, \$2,466,142 and \$2,545,226, respectively and is included in accrued expenses on the balance sheet.

#### Leases

July 2016 Lease

Effective July 1, 2016, the Company entered into a non-cancellable operating lease for laboratory and related office facilities in New York with ARE, an entity that is under common control by an entity that is a minority shareholder of the Company and whose CEO is a director of the Company. The lease provides for monthly base rent and property management fees, including rent escalations and rent holidays, plus operating expenses during the lease term, which expires on December 31, 2021. The Company records monthly rent expense on a straight-line basis from July 1, 2016 through December 31, 2021. As of December 31, 2016 and 2017 and March 31, 2018, the balance of deferred rent, representing the difference between cash rent paid and straight-line rent expense, was \$243,780, \$231,276 and \$225,999, respectively.

Total rent expense under this operating lease was \$243,780 and \$487,559 for the years ended December 31, 2016 and 2017, respectively, and \$121,890 for the three months ended March 31, 2017 and 2018. As of March 31, 2018, the aggregate future minimum rental payments under this lease are \$2.054.343.

In connection with the signing of this lease, the Company entered into a standby letter of credit agreement for \$122,866, which serves as a security deposit for the premises. The standby letter of credit expires on July 7, 2017 and is automatically renewed annually through July 7, 2021. This standby letter of credit is secured with restricted cash in a money market account (see Note 6).

#### December 2016 Lease

Effective December 15, 2016, the Company entered into another non-cancellable operating lease with ARE, expiring on October 31, 2032, for laboratory and office facilities in New York. The lease provided for monthly base rent, including rent escalations, property management fees and rent holidays, plus operating expenses during the lease term. The Company recorded monthly rent expense on a straight-line basis from December 15, 2016 through October 31, 2032. On October 26, 2017, the lease was amended, whereby the lease would terminate on March 31, 2018 and only base rent and management fees in the aggregate amount of \$563,507 would be due from November 1, 2017 through March 31, 2018. Under the amendment, the Company issued a note to ARE in the amount of \$1,442,009 (see Note 9), removed the balance of the deferred rent and

# MEIRAGTX LIMITED AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

accrued the future rent payments, all of which were recorded as rent expense at the time of the amendment, in accordance with ASC 420, Exit and Disposal Activities, as the Company had a cease use date as of the date of the amendment. As of December 31, 2016 and 2017 and March 31, 2018, the balance of deferred lease obligation, representing the difference between cash rent paid and straight-line rent expense, was \$11,380, \$0 and \$0, respectively.

Total rent expense under this operating lease was \$43,578 and \$1,660,806 for the years ended December 31, 2016 and 2017, and \$390,903 and \$0 for the three months ended March 31, 2017 and 2018, respectively.

On October 26, 2017, in connection with the amendment to the lease, the Company issued a promissory note in the amount of \$1,442,009 to ARE. The note accrued interest at the rate of 5% per annum and was due on December 31, 2018. However, if the Company had sufficient liquidity, as defined in the note, then the note, including accrued interest, would become due and payable at that time. In accordance with the sufficient liquidity provision, the Company repaid the note, plus accrued interest, in the aggregate amount of \$1,472,433 during the three-month period ended March 31, 2018.

The Company recorded interest expense in the consolidated statement of operations and comprehensive loss in connection with the note in the amount of \$17,387 for the three-month period ended March 31, 2018.

#### Convertible Note Payable

On May 1, 2017, the Company issued a convertible note in the amount of \$2,500,000 to ARE. The note had an interest at a rate of 10% per annum and was convertible into Preferred Shares at any time at the option of the holder or would automatically convert into Preferred Shares in the event of an equity investment by a mutually agreed upon institutional investor at a price per share equal to the lowest price paid per share by a purchaser of the Company's Preferred Shares. On November 2, 2017 the note was converted to 925,926 Preferred Shares at \$2.70 per share. In accordance with the terms of the convertible note, the accrued interest in the amount of \$145,833 was cancelled.

As an inducement to convert the convertible note, the Company issued a warrant to purchase 900,000 Preferred Shares, at an exercise price of \$2.70 per share, to the holder of the convertible note, which was expenses in accordance with ASC 470 (see Note 11).

#### 16. Commitments:

## **Operating Leases**

In February 2016, the Company entered into a non-cancellable operating lease, expiring in February 2021, for manufacturing and office facilities in London, UK. The lease provides for an additional five-year term at the Company's option. The lease provides for monthly base rent, plus operating expenses and real estate taxes during the lease term.

In connection with a provision in the lease requiring the Company to remove all equipment and leasehold improvements upon the termination of the lease, the Company estimated that it had an asset retirement obligation at the end of the lease term in the amount of \$306,400. The Company discounted the asset retirement obligation using an 8% discount rate and recorded an asset retirement obligation in the amount of \$205,659, which is included in leasehold improvements. As of December 31, 2017, the Company determined that it will more likely than not exercise the additional five-year option provided for in the operating lease. Therefore, the

# MEIRAGTX LIMITED AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

company revalued the asset retirement obligation over the remaining eight-year lease term and recorded a reduction in the asset retirement obligation of \$75,011. During the years ended December 31, 2016 and 2017, and the three months ended March 31, 2017 and 2018, the Company recorded \$17,247 and \$7,571 and \$4,685 and \$3,678 of interest expense, respectively. The carrying value of the asset retirement obligation at December 31, 2016 and 2017 and March 31, 2018 is \$221,254, \$178,419 and \$187,848, respectively. Total rent expense under this operating lease was \$266,698 and \$279,303 for the years ended December 31, 2016 and 2017, respectively, and \$67,259 and \$74,001 for the three months ended March 31, 2017 and 2018, respectively.

On October 1, 2017, the Company entered into a one-year non-cancellable operating lease, expiring in September 2018, for office and laboratory facilities in Leiden, Netherlands. The lease provides for monthly base rent plus operating expenses during the lease term. The lease provides for successive one-year extensions up to a maximum of four extensions. Total rent expense under this operating lease was \$0 and \$5,273 for the years ended December 31, 2016 and 2017, respectively, and \$0 and \$2,703 for the three months ended March 31, 2017 and 2018, respectively.

In June 2017, the Company entered into two non-cancellable operating leases, expiring in July 2018, for office facilities in London, UK. The lease provides for monthly base rent, rent holidays plus operating expenses and real estate taxes during the lease term. The Company records monthly rent expense on a straight-line basis from June 1, 2017 through July 23, 2018. As of December 31, 2017 and March 31, 2018, the balance of deferred lease obligation, representing the difference between cash rent paid and straight-line rent expense, was \$35,014 and \$15,489, respectively. Total rent expense under theses operating leases was \$0 and \$85,222 for the years ended December 31, 2016 and 2017, respectively, and \$0 and \$27,774 for the three months ended March 31, 2017 and 2018, respectively.

The aggregate future minimum rental payments under these leases as of December 31, 2017 are as follows:

2018	\$365,713
2019	\$293,130
2020	\$293,130
2021	\$ 24,427
Total future rent payments	\$976,400

The aggregate future minimum rental payments of all leases, including those discussed in Note 14, as of December 31, 2017 are as follows:

2018	\$1,215,723
2019	\$ 828,813
2020	\$ 847,562
2021	\$ 598,264
Total future rent payments	\$3,490,362

## Service Agreements

On April 27, 2015, the Company entered into service agreements with a senior officer and a greater than 5% shareholder of the Company. Under the terms of the agreements, the employees will receive aggregate compensation of £300,000 per annum, or approximately \$408,000 using exchange rates as of December 31, 2017. The agreements also provide for contributions to a defined contribution pension plan to be set up by the Company and a discretionary bonus. The agreements may be terminated at any time by either party by giving

# MEIRAGTX LIMITED AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

twelve-months' notice, or the Company may terminate the officer's employment effective immediately upon notice, and within 28 days making payment in lieu of notice consisting of a sum equivalent to the officer's annual salary for the relevant period. For the years ended December 31, 2016 and 2017, the Company recorded £430,000 and £724,000 or approximately \$583,000 and \$933,000, respectively, using the average exchange rates during the year ended December 31, 2016 and 2017, respectively, in research and development costs under these agreements. For the three months ended March 31, 2017 and 2018, the Company recorded £83,000 and £103,000 or approximately \$102,000 and \$145,000, respectively, using the average exchange rates during the three months ended March 31, 2017 and 2018, respectively, in research and development costs under these agreements. Future obligations to be paid under these agreements equal £34,000, or approximately \$48,000, using exchange rates as of March 31, 2018.

In connection with the service agreements, on April 24, 2015, the employees were awarded, under a share award agreement, an aggregate of 2,704,800 restricted Ordinary Shares and 750 B ordinary shares, which B ordinary shares have been converted into Ordinary Shares of the Company. Under the Share Award Agreement, such shares are subject to forfeiture ratably over a period of three years if the employee's do not remain an employee or consultant to the Company. The shares were valued at \$2.00 per share and, in accordance with ASC718, are being charged to operations as stock compensation ratably over the forfeiture period.

## **Employment Agreements**

In February 2016, the Company entered into three-year employment agreements with certain senior officers of the Company. Under the terms of the agreements, the employees will receive annual compensation in the aggregate amount of \$710,000, which was increased to a maximum aggregate amount of \$1,075,000. The employment agreements also provide for an annual guaranteed cash bonus targeted at 100% of annual compensation. The agreements also provide for discretionary annual performance bonuses targeted to be not less than 50-60% of the employee's base salary and grants of restricted stock. In January 2018 the Company's compensation committee approved a discretionary bonus in the aggregate amount of \$1,196,000. This discretionary bonus and the guaranteed bonus for 2017, in the amount of \$850,000, are subject to compensation committee approval and meeting certain future funding conditions. On February 28, 2018, the funding conditions were met.

Additionally, the agreements provide for equity incentives of up to an aggregate a maximum of 8.0% of the Company's fully diluted outstanding shares upon the attainment of certain milestones. On March 1, 2018, a funding milestone was met. Accordingly, the employees were issued an aggregate of 3% of the fully-diluted outstanding shares of the Company as of such date. (see Note 17).

The employees are also entitled to participate in all incentive and deferred compensation and employee benefit programs available to employees and executive officers of the Company. Future obligations to be paid under these agreements equal \$1,881,250, as of March 31, 2018.

## **Consulting and other Agreements**

Effective September 28, 2015, the Company entered into a three-year consulting agreement with a consultant to provide ongoing strategic advice and to serve on the Company's board of directors. In connection with the agreement, the Company issued 662,910 restricted Ordinary Shares. Under the consulting agreement, such shares are subject to forfeiture ratably over a period of three years if the consultant does not remain a consultant to the Company. The shares were valued at \$1.99 per share and are being charged to general and administrative expenses upon the expiration of each forfeiture period.

# MEIRAGTX LIMITED AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

#### Research Agreements

On April 24, 2015, the Company entered into a cooperative research and development agreement (CRADA) with the U.S. Department of Health & Human Services, as represented by the National Institute of Dental and Craniofacial Research (NIDCR) and Institute or Center of the National Institutes of Health (NIH). The CRADA provided for quarterly payments of \$21,250 for three years through April 30, 2017 and a cost per patient for each patient enrolled in the Company's xerostomia clinical trial. The CRADA was amended on March 25, 2016 to extend the term through March 25, 2021 and to extend the annual payments throughout the revised term. Research and development expenses under the CRADA for the year ended December 31, 2016 and 2017 were \$76,161 and \$115,374, respectively, and for the three months ended March 31, 2017 and 2018 were \$25,002 and \$28,348, respectively. Future obligations to be paid under the CRADA, as amended, through March 25, 2021 equal \$255,000.

On March 22, 2016, the Company entered into a five-year cooperative research and development agreement (CRADA) with the U.S. Department of Health & Human Services, as represented by the National Institute of Dental and Craniofacial Research (NIDCR) and Institute or Center of the National Institutes of Health (NIH) for the treatment of Sjogren's Syndrome associated salivary hypofunction. The CRADA provides for quarterly payments of \$104,500 for the first three years of the agreement plus a cost per patient for each patient enrolled in a clinical trial. The costs associated with years four and five of the CRADA will be determined at a later date. Total research and development expenses under this agreement for the years ended December 31, 2016 and 2017 and the three months ended March 31, 2017 and 2018, were \$325,343, \$418,000, \$104,500 and \$104,500, respectively. Future obligations to be paid under the agreement through March 22, 2019 equal \$313,500.

Effective December 5, 2016, the Company entered into a three-year research collaboration agreement with Cornell University. Pursuant to the agreement, Cornell University provides research and development under the direction of the Company. In connection with the agreement, in July 2017, the Company issued 25,000 Ordinary Shares to Cornell University, which were recorded as research and development expenses in the amount of \$17,000. The Company amended this agreement effective June 12, 2017 to add a second three-year research collaboration project through September 2019. Total research and development expenses under this agreement, as amended, for the years ended December 31, 2016 and 2017 and for the three months ended March 31, 2017 and 2018, were \$63,337 and \$1,029,904, and \$190,011 and \$448,173, respectively. Future obligations to be paid under the agreement through December 5, 2019 equal \$2,898,602.

On February 14, 2017, the Company entered into a one-year research collaboration agreement with Cornell University in the amount of \$679,473. On August 24, 2017, the agreement was amended to add an additional study in the amount of \$182,520. Total research and development expenses under this agreement for the years ended December 31, 2016 and 2017 and for the three months ended March 31, 2017 and 2018, were \$0 and \$698,307, and \$91,401 and \$77,177, respectively.

## License Agreements

Effective February 4, 2015, the Company entered into an exclusive worldwide license agreement with UCL Business, PLC ("UCL Business"), an entity that employs the Company's Chief Scientific Officer, to develop up to eight programs using certain ocular gene therapy technology. Under the terms of the agreement, as amended, the Company will pay UCL Business certain sales milestone payments, if achieved, in the aggregate amount of £39.8 million, or approximately \$54.0 million using the exchange rate at December 31, 2017, and royalties on net sales, as defined upon commercialization. Additionally, the Company is responsible for all patent prosecution and maintenance costs incurred and will also pay UCL Business an annual maintenance fee of

# MEIRAGTX LIMITED AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

£50,000, or approximately \$68,000, until the first commercial sale of a product. The agreement will terminate upon the later of (i) the last valid claim in a relevant product (ii) the expiration of regulatory exclusivity to all licensed products, or (iii) the 10<sup>th</sup> anniversary of the first commercial sale of a product. Total research and development expenses under the agreement for the years ended December 31, 2016 and 2017, and the three months ended March 31, 2017 and 2018, were \$67,775 and \$73,250, and \$61,996 and \$79,738, respectively.

On July 28, 2017, the Company entered into another worldwide license agreement with UCL Business for an additional program using certain ocular gene therapy technology. The Company will pay UCL Business certain milestone payments, royalties and annual maintenance fees under the same terms and conditions as the license dated February 4, 2015. Total research and development expenses under the agreement for the years ended December 31, 2016 and 2017, and the three months ended March 31, 2017 and 2018, were \$0, \$82,260 and \$0, respectively.

Effective March 15, 2018, the Company entered into a third exclusive worldwide license agreement with UCL Business for an additional program using certain ocular gene therapy technology. The Company issued 51,852 Preferred Shares to UCL Business, which were recorded as research and development expenses in the amount of \$140,000 during the three-month period ended March 31, 2018, and will pay UCL Business certain milestone payments, royalties and annual maintenance fees under the same terms and conditions as the license dated February 4, 2015. The Company did not incur any additional research and development expenses under the agreement during the three-month period ended March 31, 2018.

Effective January 1, 2016, the Company entered into an Agreement ("Agreement") and Plan of Merger to acquire all of the outstanding shares of BRI-Alzan from the shareholders of BRI-Alzan. In connection with the Agreement, the Company will pay certain development milestone payments if achieved, in the aggregate amount of \$4.5 million, and annual royalty payments on annual net sales following the first commercial sale of any product containing the technology acquired (see Note 3).

## 17. Employee Benefit Plans

#### **United States**

During the year ended December 31, 2016, Meira LLC participated in the Kadmon 401K Plan. On January 1, 2017, Meira LLC adopted its own defined contribution retirement plan that complies with Section 401(k) of the Internal Revenue Code. All Meira LLC employees over the age of 21 are eligible to participate in the plan after three consecutive months of service. Employees are able to defer a portion of their pay into the plan on the first day of the month on or after the day all age and service requirements have been met. The plan provides for a Company matching contribution. All eligible employees receive an employer matching contribution equal to the lesser of the amount the employee contributes to the plan or 6% of their salary up to the annual IRS limit.

## **United Kingdom**

On August 1, 2016, MeiraGTx UK II adopted a defined contribution group personal pension plan that complies with HM Revenue and Customs (HMRC) for tax relief. All MeiraGTx UK II employees are eligible to participate in the plan upon joining service. All eligible employees, if they elect to join the pension scheme, receive an employer pension contribution equal to 7.5% to 10.0% of their pensionable earnings. Currently, employees are not required to contribute, but may make optional contributions up to the annual allowance HMRC limits.

# MEIRAGTX LIMITED AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Under the HMRC requirements, current required minimum employer contributions are 2-3% but will rise to between 5-6% after April 2018 and 8-9% after April 2019.

During the years ended December 31, 2016 and 2017, and three months ended March 31, 2017 and 2018, employer contributions to all plans were \$128,281, \$252,700, \$73,838 and \$147,566, respectively.

## 18. Subsequent Events:

Management has evaluated subsequent events through the date of this filing. Based on our evaluation, the following disclosures have been made:

## **Preferred Shares**

From April 1, 2018 through April 30, 2018, the Company issued 4,706,495 Preferred Shares at an offering price of \$2.70 per share for gross proceeds in the amount of \$12,707,536.

Through and including , 2018 (the 25th day after the date of this prospectus), all dealers effecting transactions in the ordinary shares, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

## 5,000,000 Shares



## **Ordinary Shares**

PROSPECTUS

BofA Merrill Lynch
Barclays
Evercore ISI

Chardan

#### Part II

#### INFORMATION NOT REQUIRED IN PROSPECTUS

#### Item 13. Other Expenses of Issuance and Distribution.

The following table indicates the expenses to be incurred in connection with the offering described in this registration statement, other than underwriting discounts and commissions, all of which will be paid by us. All amounts are estimated except the Securities and Exchange Commission registration fee, the Financial Industry Regulatory Authority, Inc., or FINRA, filing fee and the Nasdaq listing fee.

	Amount
Securities and Exchange Commission registration fee	\$ 11,454
FINRA filing fee	14,800
Nasdaq fee	200,000
Accountants' fees and expenses	500,000
Legal fees and expenses	1,825,000
Blue Sky fees and expenses	15,000
Transfer Agent's fees and expenses	10,000
Printing and engraving expenses	100,000
Miscellaneous	73,746
Total expenses	\$ 2,750,000

#### Item 14. Indemnification of Directors and Officers.

Cayman Islands law does not limit the extent to which a company's amended and restated memorandum and articles of association may provide for indemnification of officers and directors, except to the extent any such provision may be held by the Cayman Islands courts to be contrary to public policy, such as to provide indemnification against civil fraud or the consequences of committing a crime. Our amended and restated memorandum and articles of association, which will become effective upon the completion of this offering, provide that our board of directors and officers shall be indemnified from and against all liability which they incur in execution of their duty in their respective offices, except liability incurred by reason of such directors' or officers' dishonesty, willful default or fraud.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling us pursuant to the foregoing provisions, we have been informed that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is theretofore unenforceable.

Our amended and restated memorandum and articles of association will provide:

"Every Director (including for the purposes of this Article any alternate Director appointed pursuant to the provisions of these Articles), Secretary, assistant Secretary, or other Officer (but not including the Company's auditors) and the personal representatives of the same (each an "Indemnified Person") shall be indemnified and secured harmless against all actions, proceedings, costs, charges, expenses, losses, damages or liabilities incurred or sustained by such Indemnified Person, other than by reason of such Indemnified Person's own dishonesty, willful default or fraud as determined by a court of competent jurisdiction, in or about the conduct of the Company's business or affairs (including as a result of any mistake of judgment) or in the execution or discharge of his duties, powers, authorities or discretions, including without prejudice to the generality of the foregoing,

any costs, expenses, losses or liabilities incurred by such Indemnified Person in defending (whether successfully or otherwise) any civil proceedings concerning the Company or its affairs in any court whether in the Cayman Islands or elsewhere.

- 139. No Indemnified Person shall be liable:
- (a) for the acts, receipts, neglects, defaults or omissions of any other Director or Officer or agent of the Company; or
- (b) for any loss on account of defect of title to any property of the Company; or
- (c) on account of the insufficiency of any security in or upon which any money of the Company shall be invested; or
- (d) for any loss incurred through any bank, broker or other similar Person; or
- (e) for any loss occasioned by any negligence, default, breach of duty, breach of trust, error of judgement or oversight on such Indemnified Person's part; or
- (f) for any loss, damage or misfortune whatsoever which may happen in or arise from the execution or discharge of the duties, powers, authorities, or discretions of such Indemnified Person's office or in relation thereto;

unless the same shall happen through such Indemnified Person's own dishonesty, willful default or fraud as determined by a court of competent jurisdiction."

We intend to enter into indemnification agreements with each of our directors and officers. These indemnification agreements may require us, among other things, to indemnify our directors and officers for some expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by a director or officer in any action or proceeding arising out of his or her service as one of our directors or officers, or any of our subsidiaries or any other company or enterprise to which the person provides services at our request.

We maintain a general liability insurance policy that covers certain liabilities of directors and officers of our corporation arising out of claims based on acts or omissions in their capacities as directors or officers.

In any underwriting agreement we enter into in connection with the sale of ordinary shares being registered hereby, the underwriters will agree to indemnify, under certain conditions, us, our directors, our officers and persons who control us within the meaning of the Securities Act of 1933, as amended, or the Securities Act, against certain liabilities.

## Item 15. Recent Sales of Unregistered Securities.

Set forth below is information regarding shares of capital stock issued by us within the past three years. Also included is the consideration received by us for such shares and information relating to the section of the Securities Act, or rule of the Securities and Exchange Commission, under which exemption from registration was claimed.

(a) Issuance of Capital Stock.

From April 24, 2015 through March 2, 2018, the registrant issued an aggregate (i) 1,050,831 Series A Ordinary Shares for aggregate consideration of approximately \$8.7 million, (ii) 5,611,791 Series A Ordinary Shares for nominal consideration to the registrant's founders, (iii) 1,823,569 Series A Ordinary Shares in

connection with acquisitions for aggregate consideration of approximately \$14.2 million, (iv) 182,738 Series A Ordinary Shares in connection with consulting agreements for aggregate consideration of approximately \$1.4 million, (v) 697,126 Series A Ordinary Shares in connection with service agreements for aggregate consideration of approximately \$5.4 million and (vi) 9,017 Series A Ordinary Shares in connection with license agreements for aggregate consideration of approximately \$52,000, to accredited investors, all pursuant to section 4(a)(2) of the Securities Act and Rule 506 as transactions not involving a public offering.

On July 24, 2017, the registrant issued 1,288 Series A Ordinary Shares pursuant to stock options exercised by an employee in connection with services provided to the registrant by the employee pursuant to Section 4(a)(2) and Rule 701 of the Securities Act as transactions not involving a public offering.

From October 1, 2015 through April 12, 2018, the registrant issued an aggregate (i) 10,291,361 Series C Preferred Shares for aggregate consideration of approximately \$107.8 million, including \$1.4 million in converted payables and \$1.2 million of transitions services rendered, (ii) 238,579 Series C Preferred Shares in converted promissory notes upon the cancellation of principal debt totaling \$2.5 million principal plus \$145,933 accrued interest, and (iii) 43,898 Series C Preferred Shares in connection with research and license agreements for aggregate consideration approximately \$0.5 million pursuant to Section 4(a)(2) and Rule 506 of the Securities Act.

## (b) Equity Grants.

From March 4, 2016 through January 10, 2018, the registrant granted stock options to purchase an aggregate of 1,621,360 Series A Ordinary Shares with exercise prices ranging between \$2.64 and \$7.72 per share to employees, non-employee consultants, and directors in connection with services provided to the registrant by such parties pursuant to Section 4(a)(2) and Rule 701 of the Securities Act.

### (c) Warrants.

On September 22, 2017, the registrant issued a warrant to purchase up to an aggregate of 695,696 shares of Series C preferred shares to Perceptive Life Sciences Master Fund, Ltd pursuant to Section 4(a)(2) and Rule 506 of the Securities Act as a transaction not involving a public offering.

On November 2, 2017, the registrant issued a warrant to purchase up to aggregate of 231,898 shares of Series C preferred shares to Alexandria Equities No. 7, LLC pursuant to Section 4(a)(2) and Rule 506 of the Securities Act as a transaction not involving a public offering.

## (d) Issuance of Notes.

On May 1, 2017, the registrant issued a convertible note to an entity affiliated with Alexandria Equities No. 7, LLC, in the principal amount of \$2.5 million pursuant to Section 4(a)(2) and Rule 506 of the Securities Act. On November 2, 2017, the convertible note was converted and the registrant issued 238,579 Series C preferred shares to Alexandria Equities No. 7, LLC at \$10.48 per share for an aggregate consideration of approximately \$2.5 million.

On October 26, 2017, the registrant issued a promissory note to Alexandria Equities No. 7, LLC in the principal amount of approximately \$1.4 million pursuant to Section 4(a)(2) and Rule 506 of the Securities Act.

## Item 16. Exhibits and Financial Statement Schedules.

(a) Exhibits.

<u>Exhibit</u> Number	Description of Exhibit
1.1*	Underwriting Agreement
3.1	Articles of Association of the Registrant (currently in effect)
3.2*	Form of Restated Articles of Association of the Registrant (to be effective upon consummation of the Corporate Reorganization)
3.3*	Form of Restated Articles of Association of the Registrant (to be effective upon the closing of this offering)
4.1	Specimen Share Certificate evidencing the ordinary shares of the Registrant
4.2*	Form of Shareholder Agreement (to be effective upon consummation of the Corporate Reorganization)
5.1	Opinion of Walkers
10.1#	2016 Equity Incentive Plan, as amended, and form of option agreements thereunder
10.2#	2018 Incentive Award Plan and forms of award agreements thereunder
10.3#	Non-Employee Director Compensation Program
10.4#	Form of Indemnification Agreement for Directors and Officers
10.5**	Lease Agreement, dated June 29, 2016, as amended, between MeiraGTx Limited and ARE-East River Science Park LLC
10.6**	<u>Lease Agreement, effective February 2, 2016, among MeiraGTx Limited, Moorfields Eye Hospital NHS, Foundation Trust and Kadmon Corporation LLC</u>
10.7#	Employment Agreement, dated February 15, 2016, between MeiraGTx Limited and Alexandria Forbes, Ph.D., as amended
10.8#	Employment Agreement, dated February 15, 2016 between MeiraGTx Limited and Richard Giroux, as amended
10.9#	Employment Agreement, dated April 27, 2015, between MeiraGTx Limited and Stuart Naylor, Ph.D., as amended
10.10†	License Agreement, dated May 1, 2013, as amended, among MeiraGTx Limited, Brandeis University and BRI-Alzan Inc.
10.11†	License Agreement, dated February 4, 2015, as amended, between Athena Vision Ltd. and UCL Business, Plc
10.12†	License Agreement, dated July 28, 2017, as amended, between MeiraGTx UKII Limited and UCL Business, Plc
10.13†	License Agreement, dated March 15, 2018, among MeiraGTx Limited, MeiraGTx UKII-Limited and UCL Business Plc
10.14†	Agreement and Plan of Merger, dated December 31, 2015, among MeiraGTx Acquisition Corporation, BRI-Alzan, Inc., F-Prime Inc., Gregory Petsko, Dagmar Ringe, Brandeis University and MeiraGTx Limited
10.15#	2018 Employee Share Purchase Plan
21.1	Subsidiaries of the Registrant
23.1	Consent of Ernst & Young LLP
23.3	Consent of Walkers (included in Exhibit 5.1)
24.1**	Power of Attorney (included on signature page)

- To be filed by amendment.
- Previously filed.
- Indicates management contract or compensatory plan.

  Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment pursuant to Rule 406 under the Securities Act of 1933, as amended.

(b) Financial Statement Schedules.

Schedules not listed above have been omitted because the information required to be set forth therein is not applicable or is shown in the consolidated financial statements or notes thereto.

## Item 17. Undertakings.

The undersigned registrant hereby undertakes to provide to the underwriter, at the closing specified in the underwriting agreement, certificates in such denominations and registered in such names as required by the underwriter to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned hereby undertakes that:

- (1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.
- For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of (2) prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

## **SIGNATURES**

Pursuant to the requirements of the Securities Act, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of New York, New York, on this 29th day of May, 2018.

MeiraGTx Holdings plc

By: /s/ Alexandria Forbes, Ph.D.

Alexandria Forbes, Ph.D.

President and Chief Executive Officer

## **SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities held on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
/s/ Alexandria Forbes, Ph.D. Alexandria Forbes, Ph.D.	President, Chief Executive Officer and Director (principal executive officer)	May 29, 2018
/s/ Richard Giroux Richard Giroux	Chief Operating Officer  (principal financial officer and principal accounting officer) and	Willy 23, 2010
Richard Giroux	MeiraGTx Holdings plc's authorized representative in the United States	May 29, 2018
*	Chairman of the Board of Directors	
Keith R. Harris, Ph.D.	-	May 29, 2018
*	Director	
Ellen Hukkelhoven, Ph.D.	-	May 29, 2018
*	Director	
Arnold J. Levine, Ph.D.	_ 2	May 29, 2018
*	Director	
Joel S. Marcus		May 29, 2018
*	Director	
Neil Mendoza		May 29, 2018
*	Director	
Gregory S. Moss	_ Director	May 29, 2018
*	Director	
Stuart Naylor, Ph.D.		May 29, 2018
*	Director	
Thomas E. Shenk, Ph.D.	_ 2	May 29, 2018
*By: /s/ Richard Giroux		
Attorney-in-fact		

## THE COMPANIES LAW (AS AMENDED)

## **COMPANY LIMITED BY SHARES**

ARTICLES OF ASSOCIATION

OF

MEIRAGTX HOLDINGS PLC



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REF: CM/SP/M6113-151627

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## **COMPANIES LAW (AS AMENDED)**

#### **COMPANY LIMITED BY SHARES**

#### ARTICLES OF ASSOCIATION

OF

#### MEIRAGTX HOLDINGS PLC

#### TABLE A

The Regulations contained or incorporated in Table 'A' in the First Schedule of the Companies Law shall not apply to MeiraGTx Holdings plc (the "Company") and the following Articles shall comprise the Articles of Association of the Company.

## INTERPRETATION

- In these Articles the following defined terms will have the meanings ascribed to them, if not inconsistent with the subject or context:
  - "Articles" means these articles of association of the Company, as amended or substituted from time to time.
  - "Branch Register" means any branch Register of such category or categories of Members as the Company may from time to time determine.
  - "Class" or "Classes" means any class or classes of Shares as may from time to time be issued by the Company.
  - "Companies Law" means the Companies Law (as amended) of the Cayman Islands.
  - "Directors" means the directors of the Company for the time being, or as the case may be, the directors assembled as a board or as a committee thereof.
  - "Memorandum of Association" means the memorandum of association of the Company, as amended or substituted from time to time.
  - "Office" means the registered office of the Company as required by the Companies Law.
  - "Officers" means the officers for the time being and from time to time of the Company.
  - "Ordinary Resolution" means a resolution:

- (a) passed by a simple majority of such Shareholders as, being entitled to do so, vote in person or, where proxies are allowed, by proxy at a general meeting of the Company and where a poll is taken regard shall be had in computing a majority to the number of votes to which each Shareholder is entitled; or
- (b) approved in writing by all of the Shareholders entitled to vote at a general meeting of the Company in one or more instruments each signed by one or more of the Shareholders and the effective date of the resolution so adopted shall be the date on which the instrument, or the last of such instruments, if more than one, is executed.

"paid up" means paid up as to the par value in respect of the issue of any Shares and includes credited as paid up.

"Person" means any natural person, firm, company, joint venture, partnership, corporation, association or other entity (whether or not having a separate legal personality) or any of them as the context so requires, other than in respect of a Director or Officer in which circumstances Person shall mean any person or entity permitted to act as such in accordance with the laws of the Cayman Islands.

"**Principal Register**", where the Company has established one or more Branch Registers pursuant to the Companies Law and these Articles, means the Register maintained by the Company pursuant to the Companies Law and these Articles that is not designated by the Directors as a Branch Register.

"Register" means the register of Members of the Company required to be kept pursuant to the Companies Law and includes any Branch Register(s) established by the Company in accordance with the Companies Law.

"Seal" means the common seal of the Company (if adopted) including any facsimile thereof.

"Secretary" means any Person appointed by the Directors to perform any of the duties of the secretary of the Company.

"Share" means a share in the capital of the Company. All references to "Shares" herein shall be deemed to be Shares of any or all Classes as the context may require. For the avoidance of doubt in these Articles the expression "Share" shall include a fraction of a Share.

"Shareholder" or "Member" means a Person who is registered as the holder of Shares in the Register and includes each subscriber to the Memorandum of Association pending entry in the Register of such subscriber.

"Share Premium Account" means the share premium account established in accordance with these Articles and the Companies Law.

"**signed**" means bearing a signature or representation of a signature affixed by mechanical means.

"Special Resolution" means a special resolution of the Company passed in accordance with the Companies Law, being a resolution:

- (a) passed by a majority of not less than two-thirds of such Shareholders as, being entitled to do so, vote in person or, where proxies are allowed, by proxy at a general meeting of the Company of which notice specifying the intention to propose the resolution as a special resolution has been duly given and where a poll is taken regard shall be had in computing a majority to the number of votes to which each Shareholder is entitled; or
- (b) approved in writing by all of the Shareholders entitled to vote at a general meeting of the Company in one or more instruments each signed by one or more of the Shareholders and the effective date of the special resolution so adopted shall be the date on which the instrument or the last of such instruments, if more than one, is executed.

"Treasury Shares" means Shares that were previously issued but were purchased, redeemed, surrendered or otherwise acquired by the Company and not cancelled.

- 2. In these Articles, save where the context requires otherwise:
  - (a) words importing the singular number shall include the plural number and vice versa;
  - (b) words importing the masculine gender only shall include the feminine gender and any Person as the context may require;
  - (c) the word "may" shall be construed as permissive and the word "shall" shall be construed as imperative;
  - (d) reference to a dollar or dollars or USD (or \$) and to a cent or cents is reference to dollars and cents of the United States of America;
  - (e) reference to a statutory enactment shall include reference to any amendment or re-enactment thereof for the time being in force;
  - (f) reference to any determination by the Directors shall be construed as a determination by the Directors in their sole and absolute discretion and shall be applicable either generally or in any particular case; and
  - (g) reference to "in writing" shall be construed as written or represented by any means reproducible in writing, including any form of print, lithograph, email, facsimile, photograph or telex or represented by any other substitute or format for storage or transmission for writing or partly one and partly another.
- 3. Subject to the preceding Articles, any words defined in the Companies Law shall, if not inconsistent with the subject or context, bear the same meaning in these Articles.

#### **PRELIMINARY**

- 4. The business of the Company may be commenced at any time after incorporation.
- 5. The Office shall be at such address in the Cayman Islands as the Directors may from time to time determine. The Company may in addition establish and maintain such other offices and places of business and agencies in such places as the Directors may from time to time determine.
- 6. The expenses incurred in the formation of the Company and in connection with the offer for subscription and issue of Shares shall be paid by the Company. Such expenses may be amortised over such period as the Directors may determine and the amount so paid shall be charged against income and/or capital in the accounts of the Company as the Directors shall determine.
- 7. The Directors shall keep, or cause to be kept, the Register at such place or (subject to compliance with the Companies Law and these Articles) places as the Directors may from time to time determine. In the absence of any such determination, the Register shall be kept at the Office. The Directors may keep, or cause to be kept, one or more Branch Registers as well as the Principal Register in accordance with the Companies Law, provided always that a duplicate of such Branch Register(s) shall be maintained with the Principal Register in accordance with the Companies Law.

#### **SHARES**

- 3. Subject to these Articles, all Shares for the time being unissued shall be under the control of the Directors who may:
  - (a) issue, allot and dispose of the same to such Persons, in such manner, on such terms and having such rights and being subject to such restrictions as they may from time to time determine; and
  - (b) grant options with respect to such Shares and issue warrants or similar instruments with respect thereto;
  - and, for such purposes, the Directors may reserve an appropriate number of Shares for the time being unissued.
- 9. The Directors, or the Shareholders by Ordinary Resolution, may authorise the division of Shares into any number of Classes and sub-classes and the different Classes and sub-classes shall be authorised, established and designated (or re-designated as the case may be) and the variations in the relative rights (including, without limitation, voting, dividend and redemption rights), restrictions, preferences, privileges and payment obligations as between the different Classes (if any) may be fixed and determined by the Directors or the Shareholders by Ordinary Resolution.
- 10. The Company may insofar as may be permitted by law, pay a commission to any Person in consideration of his subscribing or agreeing to subscribe whether absolutely or conditionally for any Shares. Such commissions may be satisfied by the payment of cash or the lodgement of fully or partly paid-up Shares or partly in one way and partly in the other. The Company may also pay such brokerage as may be lawful on any issue of Shares.

11. The Directors may refuse to accept any application for Shares, and may accept any application in whole or in part, for any reason or for no reason.

## MODIFICATION OF RIGHTS

- Class may, subject to any rights or restrictions for the time being attached to any Class only be materially adversely varied or abrogated with the consent in writing of the holders of not less than two-thirds of the issued Shares of the relevant Class, or with the sanction of a resolution passed at a separate meeting of the holders of the Shares of such Class by a majority of two-thirds of the votes cast at such a meeting. To every such separate meeting all the provisions of these Articles relating to general meetings of the Company or to the proceedings thereat shall, *mutatis mutandis*, apply, except that the necessary quorum shall be one or more Persons at least holding or representing by proxy one-third in nominal or par value amount of the issued Shares of the relevant Class (but so that if at any adjourned meeting of such holders a quorum as above defined is not present, those Shareholders who are present shall form a quorum) and that, subject to any rights or restrictions for the time being attached to the Shares of that Class, every Shareholder of the Class shall on a poll have one vote for each Share of the Class held by him. For the purposes of this Article the Directors may treat all the Classes or any two or more Classes as forming one Class if they consider that all such Classes would be affected in the same way by the proposals under consideration, but in any other case shall treat them as separate Classes. The Directors may vary the rights attaching to any Class without the consent or approval of Shareholders provided that the rights will not, in the determination of the Directors, be materially adversely varied or abrogated by such action.
- 13. The rights conferred upon the holders of the Shares of any Class issued with preferred or other rights shall not, subject to any rights or restrictions for the time being attached to the Shares of that Class, be deemed to be materially adversely varied or abrogated by, *inter alia*, the creation, allotment or issue of further Shares ranking *pari passu* with or subsequent to them or the redemption or purchase of any Shares of any Class by the Company.

#### **CERTIFICATES**

14. No Person shall be entitled to a certificate for any or all of his Shares, unless the Directors shall determine otherwise.

#### FRACTIONAL SHARES

15. The Directors may issue fractions of a Share and, if so issued, a fraction of a Share shall be subject to and carry the corresponding fraction of liabilities (whether with respect to nominal or par value, premium, contributions, calls or otherwise), limitations, preferences, privileges, qualifications, restrictions, rights (including, without prejudice to the generality of the foregoing, voting and

participation rights) and other attributes of a whole Share. If more than one fraction of a Share of the same Class is issued to or acquired by the same Shareholder such fractions shall be accumulated.

#### LIEN

- 16. The Company has a first and paramount lien on every Share (whether or not fully paid) for all amounts (whether presently payable or not) payable at a fixed time or called in respect of that Share. The Company also has a first and paramount lien on every Share (whether or not fully paid) registered in the name of a Person indebted or under liability to the Company (whether he is the sole registered holder of a Share or one of two or more joint holders) for all amounts owing by him or his estate to the Company (whether or not presently payable). The Directors may at any time declare a Share to be wholly or in part exempt from the provisions of this Article. The Company's lien on a Share extends to any amount payable in respect of it.
- 17. The Company may sell, in such manner as the Directors may determine, any Share on which the Company has a lien, but no sale shall be made unless an amount in respect of which the lien exists is presently payable nor until the expiration of fourteen days after a notice in writing, demanding payment of such part of the amount in respect of which the lien exists as is presently payable, has been given to the registered holder for the time being of the Share, or the Persons entitled thereto by reason of his death or bankruptcy.
- 18. For giving effect to any such sale the Directors may authorise some Person to transfer the Shares sold to the purchaser thereof. The purchaser shall be registered as the holder of the Shares comprised in any such transfer and he shall not be bound to see to the application of the purchase money, nor shall his title to the Shares be affected by any irregularity or invalidity in the proceedings in reference to the sale.
- 19. The proceeds of the sale after deduction of expenses, fees and commission incurred by the Company shall be received by the Company and applied in payment of such part of the amount in respect of which the lien exists as is presently payable, and the residue shall (subject to a like lien for sums not presently payable as existed upon the Shares prior to the sale) be paid to the Person entitled to the Shares immediately prior to the sale.

#### **CALLS ON SHARES**

- 20. The Directors may from time to time make calls upon the Shareholders in respect of any moneys unpaid on their Shares, and each Shareholder shall (subject to receiving at least fourteen days' notice specifying the time or times of payment) pay to the Company at the time or times so specified the amount called on such Shares.
- 21. The joint holders of a Share shall be jointly and severally liable to pay calls in respect thereof.
- 22. If a sum called in respect of a Share is not paid before or on the day appointed for payment thereof, the Person from whom the sum is due shall pay interest upon the sum at the rate of eight percent per annum from the day appointed for the payment thereof to the time of the actual payment, but the Directors shall be at liberty to waive payment of that interest wholly or in part.

- 23. The provisions of these Articles as to the liability of joint holders and as to payment of interest shall apply in the case of non-payment of any sum which, by the terms of issue of a Share, becomes payable at a fixed time, whether on account of the amount of the Share, or by way of premium, as if the same had become payable by virtue of a call duly made and notified.
- 24. The Directors may make arrangements on the issue of partly paid Shares for a difference between the Shareholders, or the particular Shares, in the amount of calls to be paid and in the times of payment.
- 25. The Directors may, if they think fit, receive from any Shareholder willing to advance the same all or any part of the moneys uncalled and unpaid upon any partly paid Shares held by him, and upon all or any of the moneys so advanced may (until the same would, but for such advance, become presently payable) pay interest at such rate (not exceeding without the sanction of an Ordinary Resolution, eight percent per annum) as may be agreed upon between the Shareholder paying the sum in advance and the Directors.

#### FORFEITURE OF SHARES

- 26. If a Shareholder fails to pay any call or instalment of a call in respect of any Shares on the day appointed for payment, the Directors may, at any time thereafter during such time as any part of such call or instalment remains unpaid, serve a notice on him requiring payment of so much of the call or instalment as is unpaid, together with any interest which may have accrued.
- 27. The notice shall name a further day (not earlier than the expiration of fourteen days from the date of the notice) on or before which the payment required by the notice is to be made, and shall state that in the event of non-payment at or before the time appointed the Shares in respect of which the call was made will be liable to be forfeited.
- 28. If the requirements of any such notice as aforesaid are not complied with, any Share in respect of which the notice has been given may at any time thereafter, before the payment required by notice has been made, be forfeited by a resolution of the Directors to that effect.
- 29. A forfeited Share may be sold or otherwise disposed of on such terms and in such manner as the Directors think fit, and at any time before a sale or disposition the forfeiture may be cancelled on such terms as the Directors think fit.
- 30. A Person whose Shares have been forfeited shall cease to be a Shareholder in respect of the forfeited Shares, but shall, notwithstanding, remain liable to pay to the Company all moneys which at the date of forfeiture were payable by him to the Company in respect of the Shares forfeited, but his liability shall cease if and when the Company receives payment in full of the amount unpaid on the Shares forfeited.

- 31. A statutory declaration in writing that the declarant is a Director, and that a Share has been duly forfeited on a date stated in the declaration, shall be conclusive evidence of the facts in the declaration as against all Persons claiming to be entitled to the Share.
- 32. The Company may receive the consideration, if any, given for a Share on any sale or disposition thereof pursuant to the provisions of these Articles as to forfeiture and may execute a transfer of the Share in favour of the Person to whom the Share is sold or disposed of and that Person shall be registered as the holder of the Share, and shall not be bound to see to the application of the purchase money, if any, nor shall his title to the Shares be affected by any irregularity or invalidity in the proceedings in reference to the disposition or sale.
- 33. The provisions of these Articles as to forfeiture shall apply in the case of non-payment of any sum which by the terms of issue of a Share becomes due and payable, whether on account of the amount of the Share, or by way of premium, as if the same had been payable by virtue of a call duly made and notified.

#### TRANSFER OF SHARES

- 34. The instrument of transfer of any Share shall be in any usual or common form or such other form as the Directors may determine and be executed by or on behalf of the transferor and if in respect of a nil or partly paid up Share, or if so required by the Directors, shall also be executed on behalf of the transferee and shall be accompanied by the certificate (if any) of the Shares to which it relates and such other evidence as the Directors may reasonably require to show the right of the transferor to make the transfer. The transferor shall be deemed to remain a Shareholder until the name of the transferee is entered in the Register in respect of the relevant Shares.
- 35. Subject to the terms of issue thereof, the Directors may determine to decline to register any transfer of Shares without assigning any reason therefor.
- 36. The registration of transfers may be suspended at such times and for such periods as the Directors may from time to time determine.
- 37. All instruments of transfer that are registered shall be retained by the Company, but any instrument of transfer that the Directors decline to register shall (except in any case of fraud) be returned to the Person depositing the same.

## TRANSMISSION OF SHARES

38. The legal personal representative of a deceased sole holder of a Share shall be the only Person recognised by the Company as having any title to the Share. In the case of a Share registered in the name of two or more holders, the survivors or survivor, or the legal personal representatives of the deceased holder of the Share, shall be the only Person recognised by the Company as having any title to the Share.

- 39. Any Person becoming entitled to a Share in consequence of the death or bankruptcy of a Shareholder shall upon such evidence being produced as may from time to time be required by the Directors, have the right either to be registered as a Shareholder in respect of the Share or, instead of being registered himself, to make such transfer of the Share as the deceased or bankrupt Person could have made; but the Directors shall, in either case, have the same right to decline or suspend registration as they would have had in the case of a transfer of the Share by the deceased or bankrupt Person before the death or bankruptcy.
- 40. A Person becoming entitled to a Share by reason of the death or bankruptcy of a Shareholder shall be entitled to the same dividends and other advantages to which he would be entitled if he were the registered Shareholder, except that he shall not, before being registered as a Shareholder in respect of the Share, be entitled in respect of it to exercise any right conferred by membership in relation to meetings of the Company.

## ALTERATION OF SHARE CAPITAL

- 41. The Company may from time to time by Ordinary Resolution increase the share capital by such sum, to be divided into Shares of such Classes and amount, as the resolution shall prescribe.
- 42. The Company may by Ordinary Resolution:
  - (a) consolidate and divide all or any of its share capital into Shares of a larger amount than its existing Shares;
  - (b) convert all or any of its paid up Shares into stock and reconvert that stock into paid up Shares of any denomination;
  - (c) subdivide its existing Shares, or any of them into Shares of a smaller amount provided that in the subdivision the proportion between the amount paid and the amount, if any, unpaid on each reduced Share shall be the same as it was in case of the Share from which the reduced Share is derived; and
  - (d) cancel any Shares that, at the date of the passing of the resolution, have not been taken or agreed to be taken by any Person and diminish the amount of its share capital by the amount of the Shares so cancelled.
- 43. The Company may by Special Resolution reduce its share capital and any capital redemption reserve in any manner authorised by law.

#### REDEMPTION, PURCHASE AND SURRENDER OF SHARES

- 44. Subject to the Companies Law, the Company may:
  - (a) issue Shares on terms that they are to be redeemed or are liable to be redeemed at the option of the Company or the Shareholder on such terms and in such manner as the Directors may determine;
  - (b) purchase its own Shares (including any redeemable Shares) on such terms and in such manner as the Directors may determine and agree with the Shareholder;
  - (c) make a payment in respect of the redemption or purchase of its own Shares in any manner authorised by the Companies Law, including out of its capital; and
  - (d) accept the surrender for no consideration of any paid up Share (including any redeemable Share) on such terms and in such manner as the Directors may determine.
- 45. Any Share in respect of which notice of redemption has been given shall not be entitled to participate in the profits of the Company in respect of the period after the date specified as the date of redemption in the notice of redemption.
- 46. The redemption, purchase or surrender of any Share shall not be deemed to give rise to the redemption, purchase or surrender of any other Share.
- 47. The Directors may when making payments in respect of redemption or purchase of Shares, if authorised by the terms of issue of the Shares being redeemed or purchased or with the agreement of the holder of such Shares, make such payment either in cash or in specie including, without limitation, interests in a special purpose vehicle holding assets of the Company or holding entitlement to the proceeds of assets held by the Company or in a liquidating structure.

## TREASURY SHARES

- 48. Shares that the Company purchases, redeems or acquires (by way of surrender or otherwise) may, at the option of the Company, be cancelled immediately or held as Treasury Shares in accordance with the Companies Law. In the event that the Directors do not specify that the relevant Shares are to be held as Treasury Shares, such Shares shall be cancelled.
- 49. No dividend may be declared or paid, and no other distribution (whether in cash or otherwise) of the Company's assets (including any distribution of assets to members on a winding up) may be declared or paid in respect of a Treasury Share.
- 50. The Company shall be entered in the Register as the holder of the Treasury Shares provided that:
  - (a) the Company shall not be treated as a member for any purpose and shall not exercise any right in respect of the Treasury Shares, and any purported exercise of such a right shall be void;

- (b) a Treasury Share shall not be voted, directly or indirectly, at any meeting of the Company and shall not be counted in determining the total number of issued shares at any given time, whether for the purposes of these Articles or the Companies Law, save that an allotment of Shares as fully paid bonus shares in respect of a Treasury Share is permitted and Shares allotted as fully paid bonus shares in respect of a treasury share shall be treated as Treasury Shares.
- 51. Treasury Shares may be disposed of by the Company on such terms and conditions as determined by the Directors.

#### **GENERAL MEETINGS**

- 52. The Directors may, whenever they think fit, convene a general meeting of the Company.
- 53. The Directors may cancel or postpone any duly convened general meeting at any time prior to such meeting, except for general meetings requisitioned by the Shareholders in accordance with these Articles, for any reason or for no reason at any time prior to the time for holding such meeting or, if the meeting is adjourned, the time for holding such adjourned meeting. The Directors shall give Shareholders notice in writing of any cancellation or postponement. A postponement may be for a stated period of any length or indefinitely as the Directors may determine.
- 54. General meetings shall also be convened on the requisition in writing of any Shareholder or Shareholders entitled to attend and vote at general meetings of the Company holding at least ten percent of the paid up voting share capital of the Company deposited at the Office specifying the objects of the meeting by notice given no later than 21 days from the date of deposit of the requisition signed by the requisitionists, and if the Directors do not convene such meeting for a date not later than 45 days after the date of such deposit, the requisitionists themselves may convene the general meeting in the same manner, as nearly as possible, as that in which general meetings may be convened by the Directors, and all reasonable expenses incurred by the requisitionists as a result of the failure of the Directors to convene the general meeting shall be reimbursed to them by the Company.
- 55. If at any time there are no Directors, any two Shareholders (or if there is only one Shareholder then that Shareholder) entitled to vote at general meetings of the Company may convene a general meeting in the same manner as nearly as possible as that in which general meetings may be convened by the Directors.

#### NOTICE OF GENERAL MEETINGS

56. At least seven clear days' notice in writing counting from the date service is deemed to take place as provided in these Articles specifying the place, the day and the hour of the meeting and the general nature of the business, shall be given in the manner hereinafter provided or in such other manner (if any) as may be prescribed by the Company by Ordinary Resolution to such Persons as are, under these Articles, entitled to receive such notices from the Company, but with the consent of all the Shareholders entitled to receive notice of some particular meeting and attend and vote thereat, that meeting may be convened by such shorter notice or without notice and in such manner as those Shareholders may think fit.

57. The accidental omission to give notice of a meeting to or the non-receipt of a notice of a meeting by any Shareholder shall not invalidate the proceedings at any meeting.

#### PROCEEDINGS AT GENERAL MEETINGS

- 58. All business carried out at a general meeting shall be deemed special with the exception of sanctioning a dividend, the consideration of the accounts, balance sheets, any report of the Directors or of the Company's auditors, and the fixing of the remuneration of the Company's auditors. No special business shall be transacted at any general meeting without the consent of all Shareholders entitled to receive notice of that meeting unless notice of such special business has been given in the notice convening that meeting.
- 59. No business shall be transacted at any general meeting unless a quorum of Shareholders is present at the time when the meeting proceeds to business. Save as otherwise provided by these Articles, one or more Shareholders holding at least a majority of the paid up voting share capital of the Company present in person or by proxy and entitled to vote at that meeting shall form a quorum.
- 60. If within half an hour from the time appointed for the meeting a quorum is not present, the meeting, if convened upon the requisition of Shareholders, shall be dissolved. In any other case it shall stand adjourned to the same day in the next week, at the same time and place, and if at the adjourned meeting a quorum is not present within half an hour from the time appointed for the meeting the Shareholder or Shareholders present and entitled to vote shall form a quorum.
- 61. If the Directors wish to make this facility available for a specific general meeting or all general meetings of the Company, participation in any general meeting of the Company may be by means of a telephone or similar communication equipment by way of which all Persons participating in such meeting can communicate with each other and such participation shall be deemed to constitute presence in person at the meeting.
- 62. The chairman, if any, of the Directors shall preside as chairman at every general meeting of the Company.
- 63. If there is no such chairman, or if at any general meeting he is not present within fifteen minutes after the time appointed for holding the meeting or is unwilling to act as chairman, any Director or Person nominated by the Directors shall preside as chairman, failing which the Shareholders present in person or by proxy shall choose any Person present to be chairman of that meeting.

- 64. The chairman may adjourn a meeting from time to time and from place to place either:
  - (a) with the consent of any general meeting at which a quorum is present (and shall if so directed by the meeting); or
  - (b) without the consent of such meeting if, in his sole opinion, he considers it necessary to do so to:
    - (i) secure the orderly conduct or proceedings of the meeting; or
    - (ii) give all persons present in person or by proxy and having the right to speak and / or vote at such meeting, the ability to do so,

but no business shall be transacted at any adjourned meeting other than the business left unfinished at the meeting from which the adjournment took place. When a meeting, or adjourned meeting, is adjourned for fourteen days or more, notice of the adjourned meeting shall be given in the manner provided for the original meeting. Save as aforesaid, it shall not be necessary to give any notice of an adjournment or of the business to be transacted at an adjourned meeting.

- 65. At any general meeting a resolution put to the vote of the meeting shall be decided on a show of hands, unless a poll is (before or on the declaration of the result of the show of hands) demanded by the chairman or one or more Shareholders present in person or by proxy entitled to vote, and unless a poll is so demanded, a declaration by the chairman that a resolution has, on a show of hands, been carried, or carried unanimously, or by a particular majority, or lost, and an entry to that effect in the book of the proceedings of the Company, shall be conclusive evidence of the fact, without proof of the number or proportion of the votes recorded in favour of, or against, that resolution.
- 66. If a poll is duly demanded it shall be taken in such manner as the chairman directs, and the result of the poll shall be deemed to be the resolution of the meeting at which the poll was demanded.
- 67. In the case of an equality of votes, whether on a show of hands or on a poll, the chairman of the meeting at which the show of hands takes place or at which the poll is demanded, shall be entitled to a second or casting vote.
- 68. A poll demanded on the election of a chairman of the meeting or on a question of adjournment shall be taken forthwith. A poll demanded on any other question shall be taken at such time as the chairman of the meeting directs.

# **VOTES OF SHAREHOLDERS**

- 69. Subject to any rights and restrictions for the time being attached to any Share, on a show of hands every Shareholder present in person and every Person representing a Shareholder by proxy shall, at a general meeting of the Company, each have one vote and on a poll every Shareholder and every Person representing a Shareholder by proxy shall have one vote for each Share of which he or the Person represented by proxy is the holder.
- 70. In the case of joint holders the vote of the senior who tenders a vote whether in person or by proxy shall be accepted to the exclusion of the votes of the other joint holders and for this purpose seniority shall be determined by the order in which the names stand in the Register.
- 71. A Shareholder of unsound mind, or in respect of whom an order has been made by any court having jurisdiction in lunacy, may vote in respect of Shares carrying the right to vote held by him, whether

- on a show of hands or on a poll, by his committee, or other Person in the nature of a committee appointed by that court, and any such committee or other Person, may vote in respect of such Shares by proxy.
- 72. No Shareholder shall be entitled to vote at any general meeting of the Company unless all calls, if any, or other sums presently payable by him in respect of Shares carrying the right to vote held by him have been paid.
- 73. On a poll votes may be given either personally or by proxy.
- 74. The instrument appointing a proxy shall be in writing under the hand of the appointor or of his attorney duly authorised in writing or, if the appointor is a corporation, either under Seal or under the hand of an Officer or attorney duly authorised. A proxy need not be a Shareholder.
- 75. An instrument appointing a proxy may be in any usual or common form or such other form as the Directors may approve.
- 76. The instrument appointing a proxy shall be deposited at the Office or at such other place as is specified for that purpose in the notice convening the meeting no later than the time for holding the meeting or, if the meeting is adjourned, the time for holding such adjourned meeting.
- 77. The instrument appointing a proxy shall be deemed to confer authority to demand or join in demanding a poll.
- 78. A resolution in writing signed by all the Shareholders for the time being entitled to receive notice of and to attend and vote at general meetings of the Company (or being corporations by their duly authorised representatives) shall be as valid and effective as if the same had been passed at a general meeting of the Company duly convened and held.

# CORPORATIONS ACTING BY REPRESENTATIVES AT MEETINGS

79. Any corporation which is a Shareholder or a Director may by resolution of its directors or other governing body authorise such Person as it thinks fit to act as its representative at any meeting of the Company or of any meeting of holders of a Class or of the Directors or of a committee of Directors, and the Person so authorised shall be entitled to exercise the same powers on behalf of the corporation which he represents as that corporation could exercise if it were an individual Shareholder or Director.

# **DIRECTORS**

- 80. The name(s) of the first Director(s) shall either be determined in writing by a majority (or in the case of a sole subscriber that subscriber) of, or elected at a meeting of, the subscribers of the Memorandum of Association.
- 81. The Company may by Ordinary Resolution appoint any Person to be a Director.

- 82. Subject to these Articles, a Director shall hold office until such time as he is removed from office by Ordinary Resolution.
- 83. The Company may by Ordinary Resolution from time to time fix the maximum and minimum number of Directors to be appointed but unless such numbers are fixed as aforesaid the minimum number of Directors shall be one and the maximum number of Directors shall be unlimited.
- 84. The remuneration of the Directors may be determined by the Directors or by Ordinary Resolution.
- 85. There shall be no shareholding qualification for Directors unless determined otherwise by Ordinary Resolution.
- 86. The Directors shall have power at any time and from time to time to appoint any Person to be a Director, either as a result of a casual vacancy or as an additional Director, subject to the maximum number (if any) imposed by Ordinary Resolution.

# ALTERNATE DIRECTOR

Any Director may in writing appoint another Person to be his alternate and, save to the extent provided otherwise in the form of appointment, such alternate shall have authority to sign written resolutions on behalf of the appointing Director, but shall not be authorised to sign such written resolutions where they have been signed by the appointing Director, and to act in such Director's place at any meeting of the Directors. Every such alternate shall be entitled to attend and vote at meetings of the Directors as the alternate of the Director appointing him and where he is a Director to have a separate vote in addition to his own vote. A Director may at any time in writing revoke the appointment of an alternate appointed by him. Such alternate shall not be an Officer solely as a result of his appointment as an alternate other than in respect of such times as the alternate acts as a Director. The remuneration of such alternate shall be payable out of the remuneration of the Director appointing him and the proportion thereof shall be agreed between them

#### POWERS AND DUTIES OF DIRECTORS

- 88. Subject to the Companies Law, these Articles and to any resolutions passed in a general meeting, the business of the Company shall be managed by the Directors, who may pay all expenses incurred in setting up and registering the Company and may exercise all powers of the Company. No resolution passed by the Company in general meeting shall invalidate any prior act of the Directors that would have been valid if that resolution had not been passed.
- 89. The Directors may from time to time appoint any Person, whether or not a Director to hold such office in the Company as the Directors may think necessary for the administration of the Company, including but not limited to, the office of president, one or more vice-presidents, treasurer, assistant treasurer, manager or controller, and for such term and at such remuneration (whether by way of salary or commission or participation in profits or partly in one way and partly in another), and with such powers and duties as the Directors may think fit. Any Person so appointed by the Directors may be removed by the Directors or by the Company by Ordinary Resolution. The Directors may

- also appoint one or more of their number to the office of managing director upon like terms, but any such appointment shall ipso facto terminate if any managing director ceases from any cause to be a Director, or if the Company by Ordinary Resolution resolves that his tenure of office be terminated.
- 90. The Directors may appoint any Person to be a Secretary (and if need be an assistant Secretary or assistant Secretaries) who shall hold office for such term, at such remuneration and upon such conditions and with such powers as they think fit. Any Secretary or assistant Secretary so appointed by the Directors may be removed by the Directors or by the Company by Ordinary Resolution.
- 91. The Directors may delegate any of their powers to committees consisting of such member or members of their body as they think fit; any committee so formed shall in the exercise of the powers so delegated conform to any regulations that may be imposed on it by the Directors.
- 92. The Directors may from time to time and at any time by power of attorney (whether under Seal or under hand) or otherwise appoint any company, firm or Person or body of Persons, whether nominated directly or indirectly by the Directors, to be the attorney or attorneys or authorised signatory (any such person being an "Attorney" or "Authorised Signatory", respectively) of the Company for such purposes and with such powers, authorities and discretion (not exceeding those vested in or exercisable by the Directors under these Articles) and for such period and subject to such conditions as they may think fit, and any such power of attorney or other appointment may contain such provisions for the protection and convenience of Persons dealing with any such Attorney or Authorised Signatory as the Directors may think fit, and may also authorise any such Attorney or Authorised Signatory to delegate all or any of the powers, authorities and discretion vested in him.
- 93. The Directors may from time to time provide for the management of the affairs of the Company in such manner as they shall think fit and the provisions contained in the three next following Articles shall not limit the general powers conferred by this Article.
- 94. The Directors from time to time and at any time may establish any committees, local boards or agencies for managing any of the affairs of the Company and may appoint any Person to be a member of such committees or local boards and may appoint any managers or agents of the Company and may fix the remuneration of any such Person.
- 95. The Directors from time to time and at any time may delegate to any such committee, local board, manager or agent any of the powers, authorities and discretions for the time being vested in the Directors and may authorise the members for the time being of any such local board, or any of them to fill any vacancies therein and to act notwithstanding vacancies and any such appointment or delegation may be made on such terms and subject to such conditions as the Directors may think fit and the Directors may at any time remove any Person so appointed and may annul or vary any such delegation, but no Person dealing in good faith and without notice of any such annulment or variation shall be affected thereby.
- 96. Any such delegates as aforesaid may be authorised by the Directors to sub-delegate all or any of the powers, authorities, and discretion for the time being vested in them.

97. The Directors may agree with a Shareholder to waive or modify the terms applicable to such Shareholder's subscription for Shares without obtaining the consent of any other Shareholder; provided that such waiver or modification does not amount to a variation or abrogation of the rights attaching to the Shares of such other Shareholders.

# BORROWING POWERS OF DIRECTORS

98. The Directors may exercise all the powers of the Company to borrow money and to mortgage or charge its undertaking, property and uncalled capital or any part thereof, or to otherwise provide for a security interest to be taken in such undertaking, property or uncalled capital, and to issue debentures, debenture stock and other securities whenever money is borrowed or as security for any debt, liability or obligation of the Company or of any third party.

# THE SEAL

- 99. The Seal shall not be affixed to any instrument except by the authority of a resolution of the Directors provided always that such authority may be given prior to or after the affixing of the Seal and if given after may be in general form confirming a number of affixings of the Seal. The Seal shall be affixed in the presence of a Director or a Secretary (or an assistant Secretary) or in the presence of any one or more Persons as the Directors may appoint for the purpose and every Person as aforesaid shall sign every instrument to which the Seal is so affixed in their presence.
- 100. The Company may maintain a facsimile of the Seal in such countries or places as the Directors may appoint and such facsimile Seal shall not be affixed to any instrument except by the authority of a resolution of the Directors provided always that such authority may be given prior to or after the affixing of such facsimile Seal and if given after may be in general form confirming a number of affixings of such facsimile Seal. The facsimile Seal shall be affixed in the presence of such Person or Persons as the Directors shall for this purpose appoint and such Person or Persons as aforesaid shall sign every instrument to which the facsimile Seal is so affixed in their presence and such affixing of the facsimile Seal and signing as aforesaid shall have the same meaning and effect as if the Seal had been affixed in the presence of and the instrument signed by a Director or a Secretary (or an assistant Secretary) or in the presence of any one or more Persons as the Directors may appoint for the purpose.
- 101. Notwithstanding the foregoing, a Secretary or any assistant Secretary shall have the authority to affix the Seal, or the facsimile Seal, to any instrument for the purposes of attesting authenticity of the matter contained therein but which does not create any obligation binding on the Company.

# DISQUALIFICATION OF DIRECTORS

- 102. The office of Director shall be vacated, if the Director:
  - (a) becomes bankrupt or makes any arrangement or composition with his creditors;
  - (b) dies or is found to be or becomes of unsound mind;

- (c) resigns his office by notice in writing to the Company;
- (d) is removed from office by Ordinary Resolution;
- (e) is removed from office by notice addressed to him at his last known address and signed by all of his co-Directors (not being less than two in number); or
- (f) is removed from office pursuant to any other provision of these Articles.

# PROCEEDINGS OF DIRECTORS

- 103. The Directors may meet together (either within or outside the Cayman Islands) for the despatch of business, adjourn, and otherwise regulate their meetings and proceedings as they think fit. Questions arising at any meeting shall be decided by a majority of votes. In case of an equality of votes the chairman shall have a second or casting vote. A Director may, and a Secretary or assistant Secretary on the requisition of a Director shall, at any time summon a meeting of the Directors.
- 104. A Director may participate in any meeting of the Directors, or of any committee appointed by the Directors of which such Director is a member, by means of telephone or similar communication equipment by way of which all Persons participating in such meeting can communicate with each other and such participation shall be deemed to constitute presence in person at the meeting.
- 105. The quorum necessary for the transaction of the business of the Directors may be fixed by the Directors, and unless so fixed, if there be two or more Directors the quorum shall be two, and if there be one Director the quorum shall be one. A Director represented by an alternate Director at any meeting shall be deemed to be present for the purposes of determining whether or not a quorum is present.
- 106. A Director who is in any way, whether directly or indirectly, interested in a contract or proposed contract with the Company shall declare the nature of his interest at a meeting of the Directors. A general notice given to the Directors by any Director to the effect that he is to be regarded as interested in any contract or other arrangement which may thereafter be made with that company or firm shall be deemed a sufficient declaration of interest in regard to any contract so made. A Director may vote in respect of any contract or proposed contract or arrangement notwithstanding that he may be interested therein and if he does so his vote shall be counted and he may be counted in the quorum at any meeting of the Directors at which any such contract or proposed contract or arrangement shall come before the meeting for consideration.
- 107. A Director may hold any other office or place of profit under the Company (other than the office of auditor) in conjunction with his office of Director for such period and on such terms (as to remuneration and otherwise) as the Directors may determine and no Director or intending Director shall be disqualified by his office from contracting with the Company either with regard to his tenure of any such other office or place of profit or as vendor, purchaser or otherwise, nor shall any such contract or arrangement entered into by or on behalf of the Company in which any Director is in

any way interested, be liable to be avoided, nor shall any Director so contracting or being so interested be liable to account to the Company for any profit realised by any such contract or arrangement by reason of such Director holding that office or of the fiduciary relation thereby established. A Director, notwithstanding his interest, may be counted in the quorum present at any meeting of the Directors whereat he or any other Director is appointed to hold any such office or place of profit under the Company or whereat the terms of any such appointment are arranged and he may vote on any such appointment or arrangement.

- 108. Any Director may act by himself or his firm in a professional capacity for the Company, and he or his firm shall be entitled to remuneration for professional services as if he were not a Director; provided that nothing herein contained shall authorise a Director or his firm to act as auditor to the Company.
- 109. The Directors shall cause minutes to be made in books or loose-leaf folders provided for the purpose of recording:
  - (a) all appointments of Officers made by the Directors;
  - (b) the names of the Directors present at each meeting of the Directors and of any committee of the Directors; and
  - (c) all resolutions and proceedings at all meetings of the Company, and of the Directors and of committees of Directors.
- 110. When the chairman of a meeting of the Directors signs the minutes of such meeting the same shall be deemed to have been duly held notwithstanding that all the Directors have not actually come together or that there may have been a technical defect in the proceedings.
- 111. A resolution in writing signed by all the Directors or all the members of a committee of Directors entitled to receive notice of a meeting of Directors or committee of Directors, as the case may be (an alternate Director, subject as provided otherwise in the terms of appointment of the alternate Director, being entitled to sign such a resolution on behalf of his appointer), shall be as valid and effectual as if it had been passed at a duly called and constituted meeting of Directors or committee of Directors, as the case may be. When signed a resolution may consist of several documents each signed by one or more of the Directors or his duly appointed alternate.
- 112. The continuing Directors may act notwithstanding any vacancy in their body but if and for so long as their number is reduced below the number fixed by or pursuant to these Articles as the necessary quorum of Directors, the continuing Directors may act for the purpose of increasing the number, or of summoning a general meeting of the Company, but for no other purpose.
- 113. The Directors may elect a chairman of their meetings and determine the period for which he is to hold office but if no such chairman is elected, or if at any meeting the chairman is not present within fifteen minutes after the time appointed for holding the meeting, the Directors present may choose one of their number to be chairman of the meeting.

- 114. Subject to any regulations imposed on it by the Directors, a committee appointed by the Directors may elect a chairman of its meetings. If no such chairman is elected, or if at any meeting the chairman is not present within fifteen minutes after the time appointed for holding the meeting, the committee members present may choose one of their number to be chairman of the meeting.
- 115. A committee appointed by the Directors may meet and adjourn as it thinks proper. Subject to any regulations imposed on it by the Directors, questions arising at any meeting shall be determined by a majority of votes of the committee members present and in case of an equality of votes the chairman shall have a second or casting vote.
- 116. All acts done by any meeting of the Directors or of a committee of Directors, or by any Person acting as a Director, shall notwithstanding that it be afterwards discovered that there was some defect in the appointment of any such Director or Person acting as aforesaid, or that they or any of them were disqualified, be as valid as if every such Person had been duly appointed and was qualified to be a Director.

# **DIVIDENDS**

- 117. Subject to any rights and restrictions for the time being attached to any Shares, or as otherwise provided for in the Companies Law and these Articles, the Directors may from time to time declare dividends (including interim dividends) and other distributions on Shares in issue and authorise payment of the same out of the funds of the Company lawfully available therefor.
- 118. Subject to any rights and restrictions for the time being attached to any Shares, the Company by Ordinary Resolution may declare dividends, but no dividend shall exceed the amount recommended by the Directors.
- 119. The Directors may determine, before recommending or declaring any dividend, to set aside out of the funds legally available for distribution such sums as they think proper as a reserve or reserves which shall be applicable for meeting contingencies, or for equalising dividends or for any other purpose to which those funds may be properly applied and pending such application may, at the determination of the Directors, either be employed in the business of the Company or be invested in such investments as the Directors may from time to time think fit.
- 120. Any dividend may be paid in any manner as the Directors may determine. If paid by cheque it will be sent through the post to the registered address of the Shareholder or Person entitled thereto, or in the case of joint holders, to any one of such joint holders at his registered address or to such Person and such address as the Shareholder or Person entitled, or such joint holders as the case may be, may direct. Every such cheque shall be made payable to the order of the Person to whom it is sent or to the order of such other Person as the Shareholder or Person entitled, or such joint holders as the case may be, may direct.
- 121. The Directors when paying dividends to the Shareholders in accordance with the foregoing provisions of these Articles may make such payment either in cash or in specie and may determine the extent to which amounts may be withheld therefrom (including, without limitation, any taxes, fees, expenses or other liabilities for which a Shareholder (or the Company, as a result of any action or inaction of the Shareholder) is liable).

- 122. Subject to any rights and restrictions for the time being attached to any Shares, all dividends shall be declared and paid according to the amounts paid up on the Shares, but if and for so long as nothing is paid up on any of the Shares dividends may be declared and paid according to the par value of the Shares.
- 123. If several Persons are registered as joint holders of any Share, any of them may give effectual receipts for any dividend or other moneys payable on or in respect of the Share.
- 124. No dividend shall bear interest against the Company.

# ACCOUNTS, AUDIT AND ANNUAL RETURN AND DECLARATION

- 125. The books of account relating to the Company's affairs shall be kept in such manner as may be determined from time to time by the Directors.
- 126. The books of account shall be kept at the Office, or at such other place or places as the Directors think fit, and shall always be open to the inspection of the Directors.
- 127. The Directors may from time to time determine whether and to what extent and at what times and places and under what conditions or regulations the accounts and books of the Company or any of them shall be open to the inspection of Shareholders not being Directors, and no Shareholder (not being a Director) shall have any right of inspecting any account or book or document of the Company except as conferred by law or authorised by the Directors or by Ordinary Resolution.
- 128. The accounts relating to the Company's affairs shall only be audited if the Directors so determine, in which case the financial year end and the accounting principles will be determined by the Directors.
- 129. The Directors in each year shall prepare, or cause to be prepared, an annual return and declaration setting forth the particulars required by the Companies Law and deliver a copy thereof to the Registrar of Companies in the Cayman Islands.

# **CAPITALISATION OF RESERVES**

- 130. Subject to the Companies Law and these Articles, the Directors may:
  - (a) resolve to capitalise an amount standing to the credit of reserves (including a Share Premium Account, capital redemption reserve and profit and loss account), whether or not available for distribution;

- (b) appropriate the sum resolved to be capitalised to the Shareholders in proportion to the nominal amount of Shares (whether or not fully paid) held by them respectively and apply that sum on their behalf in or towards:
  - (i) paying up the amounts (if any) for the time being unpaid on Shares held by them respectively, or
  - (ii) paying up in full unissued Shares or debentures of a nominal amount equal to that sum,
  - and allot the Shares or debentures, credited as fully paid, to the Shareholders (or as they may direct) in those proportions, or partly in one way and partly in the other, but the Share Premium Account, the capital redemption reserve and profits which are not available for distribution may, for the purposes of this Article, only be applied in paying up unissued Shares to be allotted to Shareholders credited as fully paid;
- (c) make any arrangements they think fit to resolve a difficulty arising in the distribution of a capitalised reserve and in particular, without limitation, where Shares or debentures become distributable in fractions the Directors may deal with the fractions as they think fit;
- (d) authorise a Person to enter (on behalf of all the Shareholders concerned) into an agreement with the Company providing for either:
  - (i) the allotment to the Shareholders respectively, credited as fully paid, of Shares or debentures to which they may be entitled on the capitalisation, or
  - (ii) the payment by the Company on behalf of the Shareholders (by the application of their respective proportions of the reserves resolved to be capitalised) of the amounts or part of the amounts remaining unpaid on their existing Shares,
  - and any such agreement made under this authority being effective and binding on all those Shareholders; and
- (e) generally do all acts and things required to give effect to any of the actions contemplated by this Article.

# SHARE PREMIUM ACCOUNT

- 131. The Directors shall in accordance with the Companies Law establish a Share Premium Account and shall carry to the credit of such account from time to time a sum equal to the amount or value of the premium paid on the issue of any Share.
- 132. There shall be debited to any Share Premium Account on the redemption or purchase of a Share the difference between the nominal value of such Share and the redemption or purchase price provided always that at the determination of the Directors such sum may be paid out of the profits of the Company or, if permitted by the Companies Law, out of capital.

# NOTICES

- 133. Any notice or document may be served by the Company or by the Person entitled to give notice to any Shareholder either personally, or by posting it airmail or air courier service in a prepaid letter addressed to such Shareholder at his address as appearing in the Register, or by electronic mail to any electronic mail address such Shareholder may have specified in writing for the purpose of such service of notices, or by facsimile should the Directors deem it appropriate. In the case of joint holders of a Share, all notices shall be given to that one of the joint holders whose name stands first in the Register in respect of the joint holding, and notice so given shall be sufficient notice to all the joint holders.
- 134. Any Shareholder present, either personally or by proxy, at any meeting of the Company shall for all purposes be deemed to have received due notice of such meeting and, where requisite, of the purposes for which such meeting was convened.
- 135. Any notice or other document, if served by:
  - (a) post, shall be deemed to have been served five clear days after the time when the letter containing the same is posted;
  - (b) facsimile, shall be deemed to have been served upon production by the transmitting facsimile machine of a report confirming transmission of the facsimile in full to the facsimile number of the recipient;
  - (c) recognised courier service, shall be deemed to have been served 48 hours after the time when the letter containing the same is delivered to the courier service; or
  - (d) electronic mail, shall be deemed to have been served immediately upon the time of the transmission by electronic mail.

In proving service by post or courier service it shall be sufficient to prove that the letter containing the notice or documents was properly addressed and duly posted or delivered to the courier service.

136. Any notice or document delivered or sent in accordance with the terms of these Articles shall notwithstanding that such Shareholder be then dead or bankrupt, and whether or not the Company has notice of his death or bankruptcy, be deemed to have been duly served in respect of any Share registered in the name of such Shareholder as sole or joint holder, unless his name shall at the time of the service of the notice or document, have been removed from the Register as the holder of the Share, and such service shall for all purposes be deemed a sufficient service of such notice or document on all Persons interested (whether jointly with or as claiming through or under him) in the Share.

- 137. Notice of every general meeting of the Company shall be given to:
  - (a) all Shareholders holding Shares with the right to receive notice and who have supplied to the Company an address for the giving of notices to them; and
  - (b) every Person entitled to a Share in consequence of the death or bankruptcy of a Shareholder, who but for his death or bankruptcy would be entitled to receive notice of the meeting.

No other Person shall be entitled to receive notices of general meetings.

# **INDEMNITY**

- 138. Every Director (including for the purposes of this Article any alternate Director appointed pursuant to the provisions of these Articles), Secretary, assistant Secretary, or other Officer (but not including the Company's auditors) and the personal representatives of the same (each an "Indemnified Person") shall be indemnified and secured harmless out of the assets and funds of the Company against all actions, proceedings, costs, charges, expenses, losses, damages or liabilities incurred or sustained by such Indemnified Person, other than by reason of such Indemnified Person's own dishonesty, wilful default or fraud as determined by a court of competent jurisdiction, in or about the conduct of the Company's business or affairs (including as a result of any mistake of judgment) or in the execution or discharge of his duties, powers, authorities or discretions, including without prejudice to the generality of the foregoing, any costs, expenses, losses or liabilities incurred by such Indemnified Person in defending (whether successfully or otherwise) any civil proceedings concerning the Company or its affairs in any court whether in the Cayman Islands or elsewhere.
- 139. No Indemnified Person shall be liable:
  - (a) for the acts, receipts, neglects, defaults or omissions of any other Director or Officer or agent of the Company; or
  - (b) for any loss on account of defect of title to any property of the Company; or
  - (c) on account of the insufficiency of any security in or upon which any money of the Company shall be invested; or
  - (d) for any loss incurred through any bank, broker or other similar Person; or
  - (e) for any loss occasioned by any negligence, default, breach of duty, breach of trust, error of judgement or oversight on such Indemnified Person's part; or
  - (f) for any loss, damage or misfortune whatsoever which may happen in or arise from the execution or discharge of the duties, powers, authorities, or discretions of such Indemnified Person's office or in relation thereto;

unless the same shall happen through such Indemnified Person's own dishonesty, wilful default or fraud as determined by a court of competent jurisdiction.

# NON-RECOGNITION OF TRUSTS

140. Subject to the proviso hereto, no Person shall be recognised by the Company as holding any Share upon any trust and the Company shall not, unless required by law, be bound by or be compelled in any way to recognise (even when having notice thereof) any equitable, contingent, future or partial interest in any Share or (except only as otherwise provided by these Articles or as the Companies Law requires) any other right in respect of any Share except an absolute right to the entirety thereof in each Shareholder registered in the Register, provided that, notwithstanding the foregoing, the Company shall be entitled to recognise any such interests as shall be determined by the Directors.

# WINDING UP

- 141. If the Company shall be wound up the liquidator shall apply the assets of the Company in such manner and order as he thinks fit in satisfaction of creditors' claims.
- 142. If the Company shall be wound up, the liquidator may, with the sanction of an Ordinary Resolution divide amongst the Shareholders in specie or kind the whole or any part of the assets of the Company (whether they shall consist of property of the same kind or not) and may, for such purpose set such value as he deems fair upon any property to be divided as aforesaid and may determine how such division shall be carried out as between the Shareholders or different Classes. The liquidator may, with the like sanction, vest the whole or any part of such assets in trustees upon such trusts for the benefit of the Shareholders as the liquidator, with the like sanction shall think fit, but so that no Shareholder shall be compelled to accept any assets whereon there is any liability.

# AMENDMENT OF ARTICLES OF ASSOCIATION

143. Subject to the Companies Law and the rights attaching to the various Classes, the Company may at any time and from time to time by Special Resolution alter or amend these Articles in whole or in part.

# CLOSING OF REGISTER OR FIXING RECORD DATE

144. For the purpose of determining those Shareholders that are entitled to receive notice of, attend or vote at any meeting of Shareholders or any adjournment thereof, or those Shareholders that are entitled to receive payment of any dividend, or in order to make a determination as to who is a Shareholder for any other purpose, the Directors may provide that the Register shall be closed for transfers for a stated period which shall not exceed in any case 40 days. If the Register shall be so closed for the purpose of determining those Shareholders that are entitled to receive notice of, attend or vote at a meeting of Shareholders the Register shall be so closed for at least ten days immediately preceding such meeting and the record date for such determination shall be the date of the closure of the Register.

- 145. In lieu of or apart from closing the Register, the Directors may fix in advance a date as the record date for any such determination of those Shareholders that are entitled to receive notice of, attend or vote at a meeting of the Shareholders and for the purpose of determining those Shareholders that are entitled to receive payment of any dividend the Directors may, at or within 90 days prior to the date of declaration of such dividend, fix a subsequent date as the record date for such determination.
- 146. If the Register is not so closed and no record date is fixed for the determination of those Shareholders entitled to receive notice of, attend or vote at a meeting of Shareholders or those Shareholders that are entitled to receive payment of a dividend, the date on which notice of the meeting is posted or the date on which the resolution of the Directors declaring such dividend is adopted, as the case may be, shall be the record date for such determination of Shareholders. When a determination of those Shareholders that are entitled to receive notice of, attend or vote at a meeting of Shareholders has been made as provided in this Article, such determination shall apply to any adjournment thereof.

# REGISTRATION BY WAY OF CONTINUATION

147. The Company may by Special Resolution resolve to be registered by way of continuation in a jurisdiction outside the Cayman Islands or such other jurisdiction in which it is for the time being incorporated, registered or existing. In furtherance of a resolution adopted pursuant to this Article, the Directors may cause an application to be made to the Registrar of Companies to deregister the Company in the Cayman Islands or such other jurisdiction in which it is for the time being incorporated, registered or existing and may cause all such further steps as they consider appropriate to be taken to effect the transfer by way of continuation of the Company.

# MERGERS AND CONSOLIDATION

- 148. The Company may merge or consolidate in accordance with the Companies Law.
- 149. To the extent required by the Companies Law, the Company may by Special Resolution resolve to merge or consolidate the Company.

# **DISCLOSURE**

150. The Directors, or any authorised service providers (including the Officers, the Secretary and the registered office agent of the Company), shall be entitled to disclose to any regulatory or judicial authority, or to any stock exchange on which the Shares may from time to time be listed, any information regarding the affairs of the Company including, without limitation, information contained in the Register and books of the Company.

# NAME, ADDRESS AND DESCRIPTION OF SUBSCRIBER

Walkers Nominees Limited, 190 Elgin Avenue, George Town, Grand Cayman KY1-9001, Cayman Islands

# /s/ Craig McDermaid

Craig McDermaid

as Authorised Signatory for and on behalf of Walkers Nominees Limited

Dated: 1 May 2018

/s/ Suzette Pryce

Signature of Witness

Name: Suzette Pryce

Address 190 Elgin Avenue, George Town, Grand

Cayman KY1-9001, Cayman Islands

Occupation: Secretary



TEN COM as tenants in common TEN ENT as tenants by the entireties	UNIF GIFT MIN	ACT — Custodian
JT TEN — as joint tenants with right of survivorship and not as tenants		under Úniform Gifts to Minors Act
in common		(State)
Additional abbreviation	ons may also be used though not in the above list.	
For Value Received,	hereby sell(s), assign(s) and trans	fer(s) unto
PLEASE INSERT SOCIAL SECURITY OR OTHER IDENTIFYING NUMBER OF ASSIGNEE		
IDENTIFY TING NOMBER OF ASSIGNEE		
(PLEASE PRINT OR TYPEV	VRITE NAME AND ADDRESS, INCLUDING ZIP CODE, OF AS	SSIGNEE)
Ordinary Shares represented by the within Certificate and do(es) her	eby irrevocably constitute and appoint	
		Attorney to transfer the said
shares on the books of the within named Company with full power of	of substitution in the premises.	•
Dated		
	×	
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	NOTICE: THE SIGNATURE(S) TO THIS ASSIGNME	ENT MUST CORRESPOND WITH THE
	NAME(S) AS WRITTEN UPON THE FACE PARTICULAR, WITHOUT ALTERATION ( WHATEVER.	E OF THE CERTIFICATE IN EVERY
Signature(s) Guaranteed		
THE SIGNATURE(S) MUST BE GUARANTEED BY AN ELIGIBLE GUARANTO		
INSTITUTION (BANKS, STOCKBROKERS, SAVINGS AND LOAN ASSOCIATI CREDIT UNIONS WITH MEMBERSHIP IN AN APPROVED SIGNATURE GUA MEDALLION PROGRAM), PURSUANT TO S.E.C. RULE 17Ad-15.	ONS AND RANTEE	
MEDILEION I ROGRAMI, I ORDONY 10 S.E.C. ROLE I/AU-IS.		

The following abbreviations, when used in the inscription on the face of this certificate, shall be construed as though they were written out in full according to applicable laws or regulations:

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WALKERS Page 1

29 May 2018 Our Ref: RDL/AB/151627

MeiraGTx Holdings plc c/o Walkers Corporate Limited Cayman Corporate Centre 27 Hospital Road George Town Grand Cayman KY1-9008 Cayman Islands

Dear Sirs

#### MEIRAGTX HOLDINGS PLC

We have been asked to provide this legal opinion to you with regard to the laws of the Cayman Islands in connection with the registration of a public offering by MeiraGTx Holdings plc (the "Company"), of 5,000,000 ordinary shares and up to an additional 750,000 ordinary shares which the Underwriters (as defined in schedule 1) will have a right to purchase from the Company to cover over allotments, if any, in each case with a nominal value of \$0.00003881 per share in the capital of the Company (the "Offered Shares") under the United States Securities Act of 1933, as amended (the "Securities Act") and pursuant to the terms of the Registration Statement (as defined in Schedule 1).

For the purposes of giving this opinion, we have examined and relied upon the originals or copies of the documents listed in Schedule 1.

We are Cayman Islands Attorneys at Law and express no opinion as to any laws other than the laws of the Cayman Islands in force and as interpreted at the date of this opinion.

Based upon the foregoing examinations and the assumptions and qualifications set out below and having regard to legal considerations which we consider relevant, and under the laws of the Cayman Islands, we give the following opinion in relation to the matters set out below.

- 1. The Company is an exempted company duly incorporated with limited liability, validly existing under the laws of the Cayman Islands and in good standing with the Registrar of Companies in the Cayman Islands (the "**Registrar**").
- 2. With respect to the Offered Shares, when: (a) the Corporate Reorganisation (as defined below) has been duly completed; and (b) the Shareholder Resolutions (as defined below) have been duly adopted, the Offered Shares will have been duly authorised by all necessary corporate action of the Company and upon the issue of the Offered Shares (by the entry of the name of the registered owner thereof in the Register of Members of the Company confirming that such Offered Shares have been issued credited as fully paid), delivery and payment therefore by the purchaser in accordance with the Memorandum and Articles of Association (as defined in

Walkers

190 Elgin Avenue, George Town Grand Cayman KY1-9001, Cayman Islands

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WALKERS Page 2

Schedule 1) and in the manner contemplated by the Registration Statement and the Prospectus (as each term is defined in Schedule 1), the Offered Shares will be validly created, legally issued, fully paid and non-assessable (meaning that no additional sums may be levied on the holder thereof by the Company).

The foregoing opinion is given based on the following assumptions.

- 1. The originals of all documents examined in connection with this opinion are authentic. The signatures, initials and seals on the Documents are genuine and are those of a person or persons given power to execute the Documents under the Resolutions (as defined in Schedule 1). All documents purporting to be sealed have been so sealed. All copies are complete and conform to their originals. The Documents conform in every material respect to the latest drafts of the same produced to us and, where provided in successive drafts, have been marked up to indicate all changes to such Documents.
- 2. We have relied upon the statements and representations of directors, officers and other representatives of the Company as to factual matters.
- 3. The Company will receive consideration in money or money's worth for each Offered Share offered by the Company when issued at the agreed issue price as per the terms of the Registration Statement and the Prospectus, such price in any event not being less than the stated par or nominal value of each Offered Share.
- 4. The Resolutions (defined in Schedule 1) are and shall remain in full force and effect and have not been and will not be rescinded or amended.
- 5. As at the date of issuance of the Offered Shares and in each case as contemplated by the Registration Statement and the Prospectus: (a) the corporate reorganisation as described in and contemplated by the Registration Statement and the Prospectus (the "Corporate Reorganisation") will have been duly and validly completed; (b) all shareholder resolutions of the Company (the "Shareholder Resolutions") necessary to adopt the Memorandum and Articles of Association and re-organise the share capital of the Company will have been duly and validly adopted and remain in full force and effect such that the authorised and issued share capital of the Company is as contemplated by the Registration Statement and the Prospectus; and (c) all other consents, waivers or approvals will have been obtained and remain in full force and effect in order to undertake the Corporate Reorganisation and validly adopt the Shareholder Resolutions.
- 6. Each of the Registration Statement and the Underwriting Agreement will be duly authorised, executed and delivered by or on behalf of all relevant parties prior to the issue and sale of the Offered Shares and will be legal, valid, binding and enforceable against all relevant parties in accordance with their terms under all relevant laws (other than the laws of the Cayman Islands).
- 7. All preconditions to the obligations of the parties to the Underwriting Agreement will be satisfied or duly waived prior to the issue and sale of the Offered Shares and there will be no breach of the terms of the Underwriting Agreement.

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3. There is nothing under any law (other than the laws of the Cayman Islands) which would or might affect any of the opinions set forth above.

Our opinion as to good standing is based solely upon receipt of the Certificate of Good Standing issued by the Registrar. The Company shall be deemed to be in good standing under section 200A of the Companies Law on the date of issue of the certificate if all fees and penalties under the Companies Law have been paid and the Registrar has no knowledge that the Company is in default under the Companies Law.

This opinion is limited to the matters referred to herein and shall not be construed as extending to any other matter or document not referred to herein. This opinion is given solely for your benefit and the benefit of your legal advisers acting in that capacity in relation to this transaction and may not be relied upon by any other person, other than persons entitled to rely upon it pursuant to the provisions of the Securities Act, without our prior written consent.

This opinion shall be construed in accordance with the laws of the Cayman Islands.

We hereby consent to the filing of this opinion as an exhibit to the Registration Statement. We also hereby consent to the reference to this firm in the Prospectus.

Yours faithfully

# WALKERS

# WALKERS Page 4 SCHEDULE 1

# LIST OF DOCUMENTS EXAMINED

- 1. The Certificate of Incorporation dated 1 May 2018 and the Amended and Restated Memorandum and Articles of Association, to be in effect upon the consummation of the sale of the Offered Shares (the "Memorandum and Articles of Association").
- 2. The Cayman Online Registry Information System (CORIS), the Cayman Islands' General Registry's online database, searched on 28 May 2018.
- 3. A Certificate of Good Standing dated 28 May 2018 in respect of the Company issued by the Registrar (the "Certificate of Good Standing").
- 4. Copies of the executed written resolutions of the Director of the Company dated 25 May 2018 approving the offering for sale of the Offered Shares (the "Resolutions") and the corporate records of the Company maintained at its registered office in the Cayman Islands.
- 5. Copies of the following documents (the "**Documents**"):
  - (a) the prospectus of the Company May 29, 2018 (the "**Prospectus**"), forming a part of the Registration Statement (as defined below) filed by the Company with the United States Securities and Exchange Commission ("**SEC**") in respect of the initial public offering and sale by the Company of the Offered Shares;
  - (b) the Registration Statement on Form S-1 originally filed on May 29, 2018 by the Company with the SEC registering the Offered Shares under the Securities Act (as filed and amended, the "**Registration Statement**");
  - (c) a draft form of Underwriting Agreement to be entered into between the Company and Merrill Lynch, Pierce, Fenner & Smith Incorporated and Barclays Capital Inc., as representatives of the several underwriters named therein (the "**Underwriters**") (the "**Underwriting Agreement**"); and
  - (d) such other documents as we have deemed necessary to render the opinions set forth herein.

#### MEIRAGTX LIMITED

# 2016 EQUITY INCENTIVE PLAN

# 1. Purpose.

The purpose of the Plan is to advance the interests of the Company's shareholders by enhancing the Company's ability to attract, retain and motivate persons who make (or are expected to make) important contributions to the Company by providing such persons with equity ownership opportunities and thereby better aligning the interests of such persons with those of the Company's shareholders. Capitalized terms used in the Plan are defined in Section 11 below.

# 2. Eliaibility.

Service Providers are eligible to be granted Awards under the Plan, subject to the limitations described herein.

# 3. Administration and Delegation.

(a) *Administration*. The Plan will be administered by the Administrator. The Administrator shall have authority to determine which Service Providers will receive Awards, to grant Awards and to set all terms and conditions of Awards (including, but not limited to, vesting, exercise and forfeiture provisions). In addition, the Administrator shall have the authority to take all actions and make all determinations contemplated by the Plan and to adopt, amend and repeal such administrative rules, guidelines and practices relating to the Plan as it shall deem advisable. The Administrator may correct any defect or ambiguity, supply any omission or reconcile any inconsistency in the Plan or any Award in the manner and to the extent it shall deem necessary or appropriate to carry the Plan and any Awards into effect, as determined by the Administrator. The Administrator shall make all determinations under the Plan in the Administrator's sole discretion and all such determinations shall be final and binding on all persons having or claiming any interest in the Plan or in any Award

(b) *Appointment of Committees*. To the extent permitted by Applicable Laws, the Board may delegate any or all of its powers under the Plan to one or more Committees. The Board may abolish any Committee at any time and re-vest in itself any previously delegated authority.

# 4. Common Stock Available for Awards.

(a) *Number of Shares*. Subject to adjustment under Section 8 hereof, Awards may be made under the Plan covering up to 6,292,500 shares of Common Stock. If any Award expires or lapses or is terminated, surrendered or canceled without having been fully exercised or is forfeited in whole or in part (including, without limitation, as the result of shares of Common Stock subject to such Award being repurchased by the Company at or below the original issuance price), in any case in a manner that results in any shares of Common Stock covered by such Award not being issued or being so reacquired by the Company, the unused Common Stock covered by such Award shall again be available for the grant of Awards under the Plan. Further, shares of Common Stock delivered (either by actual delivery or attestation) to the Company by a Participant to satisfy the applicable exercise or purchase price of an Award and/or to satisfy any applicable tax withholding obligation (including, without limitation, shares retained by the Company from the Award being exercised or purchased and/or creating the tax obligation) shall be added to the number of shares of Common Stock available for the grant of Awards under the Plan. However, in the case of Incentive Stock Options (as hereinafter defined), the foregoing provisions shall be subject to any limitations under the Code. Shares of Common Stock issued under the Plan may consist in whole or in part of unissued shares, shares purchased on the open market, shares purchased from any employee benefit trust or employee share trust or treasury shares.

(b) *Substitute Awards*. In connection with a merger or consolidation of an entity with the Company or the acquisition by the Company of property or share of an entity, the Administrator may grant Awards in substitution for any options or other share or share-based awards granted prior to such merger or consolidation by such entity or an affiliate thereof. Substitute Awards may be granted on such terms as the Administrator deems appropriate in the circumstances, notwithstanding any limitations on Awards contained in the Plan. Substitute Awards shall not count against the overall share limit set forth in Section 4(a) hereof, except as may be required by reason of Section 422 of the Code.

# 5. Stock Options.

- (a) *General*. The Administrator may grant Options to any Service Provider, subject to the limitations on Incentive Stock Options described below. The Administrator shall determine the number of shares of Common Stock to be covered by each Option, the exercise price of each Option and the conditions and limitations applicable to the exercise of each Option, including, without limitation, conditions relating to Applicable Laws, as it considers necessary or advisable.
- (b) *Incentive Stock Options*. The Administrator may grant Options intended to qualify as Incentive Stock Options only to Employees, which for this purpose only includes employees of the Company's present or future "parent corporations" or "subsidiary corporations" as defined in Sections 424(e) or (f) of the Code, respectively. All Options intended to qualify as Incentive Stock Options shall be subject to and shall be construed consistently with the requirements of Section 422 of the Code. Neither the Company nor the Administrator shall have any liability to a Participant, or any other party, (i) if an Option (or any part thereof) which is intended to qualify as an Incentive Stock Option fails to qualify as an Incentive Stock Option or (ii) for any action or omission by the Administrator that causes an Option not to qualify as an Incentive Stock Option, including, without limitation, the conversion of an Incentive Stock Option to a Non-Qualified Stock Option or the grant of an Option intended as an Incentive Stock Option that fails to satisfy the requirements under the Code applicable to an Incentive Stock Option. Any Option that is intended to qualify as an Incentive Stock Option, but fails to so qualify for any reason, including, without limitation, the portion of any Option becoming exercisable in excess of the \$100,000 limitation described in Treasury Regulation Section 1.422-4, shall be treated as a Non-Qualified Stock Option for all purposes.
- (c) *Exercise Price*. The Administrator shall establish the exercise price of each Option and specify the exercise price in the applicable Award Agreement. The exercise price shall be not less than par value per share of Common Stock on the date the Option is granted. In the case of an Incentive Stock Option granted to an Employee who, at the time of grant of the Option, owns (or is treated as owning under Section 424 of the Code) shares representing more than 10% of the voting power of all classes of shares of the Company (or a "parent corporation" or "subsidiary corporation" thereof within the meaning of Sections 424(e) or 424(f) of the Code, respectively), the per share exercise price shall be no less than 110% of the Fair Market Value on the date the Option is granted.
- (d) *Duration of Options*. Each Option shall be exercisable at such times and subject to such terms and conditions as the Administrator may specify in the applicable Award Agreement, provided that the term of any Option shall not exceed ten years. In the case of an Incentive Stock Option granted to an employee who, at the time of grant of the Option, owns (or is treated as owning under Section 424 of the Code) shares representing more than 10% of the voting power of all classes of shares of the Company (or a "parent corporation" or "subsidiary corporation" thereof within the meaning of Sections 424(e) or 424(f) of the Code, respectively), the term of the Option shall not exceed five years.

- (e) Exercise of Option; Notification of Disposition. Options may be exercised by delivery to the Company, at such time(s) as may be specified in the applicable Award Agreement or by the Administrator, of a written notice of exercise, in a form approved by the Administrator (which may be an electronic form), signed by the person authorized to exercise the Option, together with payment in full (i) as specified in Section 5(f) hereof for the number of shares for which the Option is exercised and (ii) as specified in Section 9(e) hereof for any applicable withholding taxes. Unless otherwise determined by the Administrator, an Option may not be exercised for a fraction of a share of Common Stock. If an Option is designated as an Incentive Stock Option, the Participant shall give prompt notice to the Company of any disposition or other transfer of any shares of Common Stock acquired from the Option if such disposition or transfer is made (i) within two years from the grant date with respect to such Option or (ii) within one year after the transfer of such shares to the Participant (other than any such disposition made in connection with a change in control). Such notice shall specify the date of such disposition or other transfer and the amount realized, in cash, other property, assumption of indebtedness or other consideration, by the Participant in such disposition or other transfer.
- (f) *Payment Upon Exercise*. Common Stock purchased upon the exercise of an Option granted under the Plan shall be paid for in cash, by wire transfer of immediately available funds or by check, payable to the order of the Company, or, subject to Section 10(h), any Company insider trading policy (including, without limitation, any blackout periods) and Applicable Laws, by:
  - (i) If the Company is a Publicly Listed Company, unless the Administrator otherwise determines, (A) delivery of an irrevocable and unconditional undertaking by a broker acceptable to the Company to deliver promptly to the Company sufficient funds to pay the exercise price, or (B) delivery by the Participant to the Company of a copy of irrevocable and unconditional instructions to a broker acceptable to the Company to deliver promptly to the Company cash or a check sufficient to pay the exercise price, provided in either case, that such amount is paid to the Company at such time as may be required by the Administrator;
  - (ii) delivery (either by actual delivery or attestation) of shares of Common Stock owned by the Participant valued at their Fair Market Value, provided (A) such method of payment is then permitted under Applicable Laws, (B) such Common Stock, if acquired directly from the Company, was owned by the Participant for such minimum period of time, if any, as may be established by the Company at any time, and (C) such Common Stock is not subject to any repurchase, forfeiture, unfulfilled vesting or other similar requirements;
  - (iii) to the extent permitted by the Administrator, surrendering shares of Common Stock then issuable upon exercise of the Option valued at their Fair Market Value on the date of exercise;
  - (iv) to the extent permitted by the Administrator, delivery of a promissory note of the Participant to the Company on terms determined by the Administrator;
  - (v) to the extent permitted by the Administrator, delivery of property of any other kind which constitutes good and valuable consideration as determined by the Administrator; or
    - (vi) any combination of the above permitted forms of payment (including, without limitation, cash or check).

Notwithstanding the foregoing, the Company may limit a Participant's right to pay for Common Stock in cash or by check upon exercise of an Option to the extent restricted by any applicable exchange control laws or requirements.

(g) *Early Exercise of Options*. The Administrator may provide in the terms of an Award Agreement that the Service Provider may exercise an Option in whole or in part prior to the full vesting of the Option in exchange for unvested shares of Restricted Stock with respect to any unvested portion of the Option so exercised. Shares of Restricted Stock acquired upon the exercise of any unvested portion of an Option shall be subject to such terms and conditions as the Administrator shall determine.

# 6. Restricted Stock; Restricted Stock Units.

- (a) *General*. The Administrator may grant Restricted Stock, or the right to purchase Restricted Stock, to any Service Provider, subject to the right of the Company to repurchase all or part of such shares at their issue price or other stated or formula price from the Participant (or to require forfeiture of such shares if issued at no cost) in the event that conditions specified by the Administrator in the applicable Award Agreement are not satisfied prior to the end of the applicable restriction period or periods established by the Administrator for such Award. In addition, the Administrator may grant to Service Providers Restricted Stock Units, which may be subject to vesting and forfeiture conditions during applicable restriction period or periods, as set forth in an applicable Award Agreement.
- (b) *Terms and Conditions for All Restricted Stock and Restricted Stock Unit Awards*. The Administrator shall determine and set forth in the applicable Award Agreement the terms and conditions applicable to each Restricted Stock and Restricted Stock Unit Award, including, without limitation, the conditions for vesting and repurchase (or forfeiture) and the issue price, in each case, if any.
  - (c) Additional Provisions Relating to Restricted Stock.
  - (i) *Dividends*. Participants holding shares of Restricted Stock will be entitled to all ordinary cash dividends paid with respect to such shares to the extent such dividends have a record date that is on or after the date on which the Participant to whom such Restricted Shares are granted becomes the record holder of such Restricted Shares, unless otherwise provided by the Administrator in the applicable Award Agreement. In addition, unless otherwise provided by the Administrator, if any dividends or distributions are paid in shares, or consist of a dividend or distribution to holders of Common Stock of property other than an ordinary cash dividend, the shares or other property will be subject to the same restrictions on transferability and forfeitability as the shares of Restricted Stock with respect to which they were paid. Each dividend payment will be made as provided in the applicable Award Agreement, but in no event later than the end of the calendar year in which the dividends are paid to shareholders of that class of shares or, if later, the 15th day of the third month following the later of (A) the date the dividends are paid to shareholders of that class of shares, and (B) the date the dividends are no longer subject to forfeiture.
  - (ii) *Share Certificates*. The Company may require that any share certificates issued in respect of shares of Restricted Stock be deposited in escrow by the Participant, together with a duly executed, but undated, repurchase/transfer form, with the Company (or its designee).
    - (d) Additional Provisions Relating to Restricted Stock Units.
  - (i) *Settlement*. Upon the vesting of a Restricted Stock Unit, the Participant shall be entitled to receive from the Company one share of Common Stock or an amount of cash or other property equal to the Fair Market Value of one share of Common Stock on the settlement date, as the Administrator shall determine and as provided in the applicable Award Agreement. The Administrator may provide that settlement of Restricted Stock Units shall occur upon or as soon as reasonably practicable after the vesting of the Restricted Stock Units or shall instead be deferred, on a mandatory basis or at the election of the Participant, in a manner that complies with Section 409A.

- (ii) *Voting Rights*. A Participant shall have no voting rights with respect to any Restricted Stock Units unless and until shares are delivered in settlement thereof.
- (iii) *Dividend Equivalents*. To the extent provided by the Administrator, a grant of Restricted Stock Units may provide a Participant with the right to receive Dividend Equivalents. Dividend Equivalents may be paid currently or credited to an account for the Participant, may be settled in cash and/or shares of Common Stock and may be subject to the same restrictions on transfer and forfeitability as the Restricted Stock Units with respect to which the Dividend Equivalents are paid, as determined by the Administrator, subject, in each case, to such terms and conditions as the Administrator shall establish and set forth in the applicable Award Agreement.

#### 7. Other Stock-Based Awards.

Other Stock-Based Awards may be granted hereunder to Participants, including, without limitation, Awards entitling Participants to receive shares of Common Stock to be delivered in the future. Such Other Stock-Based Awards shall also be available as a form of payment in the settlement of other Awards granted under the Plan, as stand-alone payments and/or as payment in lieu of compensation to which a Participant is otherwise entitled. Other Stock-Based Awards may be paid in shares of Common Stock, cash or other property, as the Administrator shall determine. Subject to the provisions of the Plan, the Administrator shall determine the terms and conditions of each Other Stock-Based Award, including, without limitation, any purchase price, transfer restrictions, vesting conditions and other terms and conditions applicable thereto, which shall be set forth in the applicable Award Agreement.

# 8. Adjustments for Changes in Common Stock and Certain Other Events.

- (a) In connection with the occurrence of any Equity Restructuring, and notwithstanding anything to the contrary in this Section 8, the Administrator will equitably adjust each outstanding Award, which adjustments may include adjustments to the number and type of securities subject to each outstanding Award and/or the exercise price or grant price thereof, if applicable, the grant of new Awards to Participants, and/or the making of a cash payment to Participants, as the Administrator deems appropriate to reflect such Equity Restructuring. The adjustments provided under this Section 8(a) shall be nondiscretionary and shall be final and binding on the affected Participant and the Company; provided that whether an adjustment is equitable shall be determined by the Administrator.
- (b) In the event that the Administrator determines that any dividend or other distribution (whether in the form of cash, Common Stock, other securities, or other property), reorganization, merger, amalgamation, consolidation, combination, repurchase, recapitalization, liquidation, dissolution, or sale, transfer, exchange or other disposition of all or substantially all of the assets of the Company, or sale or exchange of Common Stock or other securities of the Company, issuance of warrants or other rights to purchase Common Stock or other securities of the Company, or other similar corporate transaction or event, as determined by the Administrator, affects the Common Stock such that an adjustment is determined by the Administrator to be appropriate in order to prevent dilution or enlargement of the benefits or potential benefits intended by the Company to be made available under the Plan or with respect to any Award, then the Administrator may, in such manner as it may deem equitable, adjust any or all of:

- (i) the number and kind of shares of Common Stock (or other securities or property) with respect to which Awards may be granted or awarded (including, but not limited to, adjustments of the limitations in Section 4 hereof on the maximum number and kind of shares which may be issued);
  - (ii) the number and kind of shares of Common Stock (or other securities or property) subject to outstanding Awards;
  - (iii) the grant or exercise price with respect to any Award; and
- (iv) the terms and conditions of any Awards (including, without limitation, any applicable financial or other performance "targets" specified in an Award Agreement).
- (c) In the event of any transaction or event described in Section 8(b) hereof (including, without limitation, any change in control) or any unusual or nonrecurring transaction or event affecting the Company or the financial statements or financial condition of the Company, or any change in any Applicable Laws or accounting principles, the Administrator, on such terms and conditions as it deems appropriate, either by the terms of the Award or by action taken prior to the occurrence of such transaction or event and either automatically or upon the Participant's request, is hereby authorized to take any one or more of the following actions whenever the Administrator determines that such action is appropriate in order to (x) prevent dilution or enlargement of the benefits or potential benefits intended by the Company to be made available under the Plan or with respect to any Award granted or issued under the Plan, (y) to facilitate such transaction or event or (z) give effect to such changes in Applicable Laws or accounting principles:
  - (i) To provide for the cancellation of any such Award in exchange for either an amount of cash or other property with a value equal to the amount that could have been obtained upon the exercise or settlement of the vested portion of such Award or realization of the Participant's rights under the vested portion of such Award, as applicable; provided that, if the amount that could have been obtained upon the exercise or settlement of the vested portion of such Award or realization of the Participant's rights, in any case, is equal to or less than zero, then the vested portion of such Award may be terminated without payment;
  - (ii) To provide that such Award shall vest and, to the extent applicable, be exercisable as to all shares covered thereby, notwithstanding anything to the contrary in the Plan or the provisions of such Award;
  - (iii) To provide that such Award be assumed by the successor or survivor corporation, or a parent or subsidiary thereof, or shall be substituted for by awards covering the stock or shares of the successor or survivor corporation, or a parent or subsidiary thereof, with appropriate adjustments as to the number and kind of shares and applicable exercise or purchase price, in all cases, as determined by the Administrator;
  - (iv) To make adjustments in the number and type of shares of Common Stock (or other securities or property) subject to outstanding Awards, and/or in the terms and conditions of (including, without limitation, the grant or exercise price), and the criteria included in, outstanding Awards which may be granted in the future;
    - (v) To replace such Award with other rights or property selected by the Administrator; and/or

- (vi) To provide that the Award will terminate and cannot vest, be exercised or become payable after the applicable event.
- (d) In the event of any pending share dividend, share split, combination or exchange of shares, merger, amalgamation, consolidation or other distribution (other than normal cash dividends) of Company assets to shareholders, or any other change affecting the Common Stock or the share price of the Common Stock, including, without limitation, any Equity Restructuring, for reasons of administrative convenience the Administrator may refuse to permit the exercise of any Award during a period of up to thirty days prior to the consummation of any such transaction.
- (e) Except as expressly provided in the Plan or pursuant to action of the Administrator under the Plan, no Participant shall have any rights by reason of any subdivision or consolidation of shares of any class, the payment of any dividend, any increase or decrease in the number of shares of any class or any dissolution, liquidation, merger, or consolidation of the Company or any other corporation. Except as expressly provided in the Plan or pursuant to action of the Administrator under the Plan, no issuance by the Company of shares of any class, or securities convertible into shares of any class, shall affect, and no adjustment by reason thereof shall be made with respect to, the number of shares of Common Stock subject to an Award or the grant or exercise price of any Award. The existence of the Plan, any Award Agreements and the Awards granted hereunder shall not affect or restrict in any way the right or power of the Company to make or authorize (i) any adjustment, recapitalization, reorganization or other change in the Company's capital structure or its business, (ii) any merger, consolidation dissolution or liquidation of the Company or sale of Company assets or (iii) any sale or issuance of securities, including, without limitation, securities with rights superior to those of the Common Stock or which are convertible into or exchangeable for Common Stock. The Administrator may treat Participants and Awards (or portions thereof) differently under this Section 8.

# 9. General Provisions Applicable to Awards.

- (a) *Transferability*. Except as the Administrator may otherwise determine or provide in an Award Agreement or otherwise, in any case in accordance with Applicable Laws, neither Awards nor any interest therein shall not be sold, assigned, transferred, pledged or otherwise encumbered by the person to whom they are granted, either voluntarily or by operation of law, except by will or the laws of descent and distribution, and, during the life of the Participant, shall be exercisable only by the Participant. Except as the Administrator may otherwise determine or provide in an Award Agreement or otherwise, in any case in accordance with Applicable Laws, shares of Common Stock acquired by a Participant in connection with Awards shall not be sold, assigned, transferred, pledged or otherwise encumbered by the person to whom such shares are issued, either voluntarily or by operation of law. References to a Participant, to the extent relevant in the context, shall include references to authorized transferees.
- (b) *Documentation*. Each Award shall be evidenced in an Award Agreement, which may be in such form (written, electronic or otherwise) as the Administrator shall determine. Each Award may contain terms and conditions in addition to those set forth in the Plan.
- (c) *Discretion*. Except as otherwise provided by the Plan, each Award may be made alone or in addition or in relation to any other Award. The terms of each Award to a Participant need not be identical, and the Administrator need not treat Participants or Awards (or portions thereof) uniformly.
- (d) *Termination of Status*. The Administrator shall determine the effect on an Award of Disability, death, retirement, authorized leave of absence or any other change or purported change in a Participant's Service Provider status and the extent to which, and the period during which, the Participant, the Participant's legal representative, conservator, estate representative, guardian or Designated Beneficiary may exercise rights under the Award, if applicable. The Administrator may determine that, on the occurrence of any of the events mentioned above, the Award will lapse and cease to be exercisable.

- (e) Withholding. Each Participant shall pay to the Company, or make provision satisfactory to the Administrator for payment of, any taxes required by law to be withheld in connection with Awards to such Participant no later than the date of the event creating the tax liability. Except as the Administrator may otherwise determine, all such payments shall be made in cash, by wire transfer of immediately available funds or by certified check. Notwithstanding the foregoing, Participants may satisfy such tax obligations, subject to Section 10(h), any Company insider trading policy (including blackout periods) and Applicable Laws, (i) to the extent permitted by the Administrator, in whole or in part by delivery of shares of Common Stock, including shares retained from the Award creating the tax obligation, valued at their Fair Market Value, and (ii) if there is a public market for shares of Common Stock at the time the tax obligations are satisfied, unless the Administrator otherwise determines, (A) delivery (including, without limitation, telephonically to the extent permitted by the Company) of an irrevocable and unconditional undertaking by a broker acceptable to the Company to deliver promptly to the Company sufficient funds to satisfy the tax obligations, or (B) delivery by the Participant to the Company of a copy of irrevocable and unconditional instructions to a broker acceptable to the Company to deliver promptly to the Company cash or a check sufficient to satisfy the tax withholding; provided that such amount is paid to the Company at such time as may be required by the Administrator. The Company may, to the extent permitted by Applicable Laws, deduct any such tax obligations based on minimum statutory withholding rates from any payment of any kind otherwise due to a Participant.
- (f) Amendment of Award. The Administrator may amend, modify or terminate any outstanding Award, including but not limited to, substituting therefor another Award of the same or a different type, changing the date of exercise or settlement, and converting an Incentive Stock Option to a Non-Qualified Stock Option. The Participant's consent to such action shall be required unless (i) the Administrator determines that the action, taking into account any related action, would not materially and adversely affect the Participant, or (ii) the change is permitted under Section 8 and 10(f) hereof.
- (g) Conditions on Delivery of Common Stock. The Company will not be obligated to deliver any shares of Common Stock pursuant to the Plan or to remove restrictions from shares previously delivered under the Plan until (i) all conditions of the Award have been met or removed to the satisfaction of the Company, (ii) in the opinion of the Company's counsel, all other legal matters in connection with the issuance and delivery of such shares have been satisfied, including, without limitation, any applicable securities laws and any applicable stock exchange or stock market rules and regulations, and (iii) the Participant has executed and delivered to the Company such representations or agreements as the Administrator deems necessary or appropriate to satisfy the requirements of any Applicable Laws. The inability of the Company to obtain authority from any regulatory body having jurisdiction, which authority is determined by the Administrator to be necessary to the lawful issuance and sale of any securities hereunder, shall relieve the Company of any liability in respect of the failure to issue or sell such shares as to which such requisite authority shall not have been obtained.
- (h) *Acceleration*. The Administrator may at any time provide that any Award shall become immediately vested and/or exercisable in full or in part, free of some or all restrictions or conditions, or otherwise realizable in full or in part, as the case may be.

#### 10. Miscellaneous.

(a) *No Right To Employment or Other Status*. No person shall have any claim or right to be granted an Award, and the grant of an Award shall not be construed as giving a Participant the right to continued employment or any other relationship with the Company. The Company expressly reserves the right at any time to dismiss or otherwise terminate its relationship with a Participant free from any liability or claim under the Plan or any Award, except as expressly provided in an applicable Award Agreement.

- (b) No Rights As Shareholder; Certificates. Subject to the provisions of the applicable Award Agreement, no Participant or Designated Beneficiary shall have any rights as a shareholder with respect to any shares of Common Stock to be distributed with respect to an Award until becoming the record holder of such shares. Notwithstanding any other provision of the Plan, unless otherwise determined by the Administrator or required by any Applicable Laws, the Company shall not be required to deliver to any Participant certificates evidencing shares of Common Stock issued in connection with any Award and instead such shares of Common Stock may be recorded in the share register and/or other applicable books of the Company (or, as applicable, its transfer agent or share plan administrator). The Company may place legends on share certificates issued under the Plan deemed necessary or appropriate by the Administrator in order to comply with Applicable Laws.
- (c) *Effective Date and Term of Plan*. The Plan shall become effective on the date on which it is adopted by the Board following approval of the same by the Company's shareholders. No Awards shall be granted under the Plan after the completion of ten years from the earlier of (i) the date on which the Plan was adopted by the Board or (ii) the date the Plan was approved by the Company's shareholders, but Awards previously granted may extend beyond that date in accordance with the terms of the Plan.
- (d) *Amendment of Plan.* The Administrator may amend, suspend or terminate the Plan or any portion thereof at any time; provided that no amendment of the Plan shall materially and adversely affect (as determined by the Administrator) any Award outstanding at the time of such amendment without the consent of the affected Participant. Awards outstanding under the Plan at the time of any suspension or termination of the Plan shall continue to be governed in accordance with the terms of the Plan and the applicable Award Agreement, as in effect prior to such suspension or termination. The Board shall obtain shareholder approval of any Plan amendment to the extent necessary to comply with Applicable Laws.
- (e) *Provisions for Foreign Participants*. The Administrator may modify Awards granted to Participants who are foreign nationals or employed outside the United States or establish subplans or procedures under the Plan to address differences in laws, rules, regulations or customs of such foreign jurisdictions with respect to tax, securities, currency, employee benefit or other matters.
  - (f) Section 409A.
  - (i) *General*. The Company intends that all Awards be structured in compliance with, or to satisfy an exemption from, Section 409A, such that no adverse tax consequences, interest, or penalties under Section 409A apply in connection with any Awards. Notwithstanding anything herein or in any Award Agreement to the contrary, the Administrator may, without a Participant's prior consent, amend this Plan and/or Awards, adopt policies and procedures, or take any other actions (including, without limitation, amendments, policies, procedures and actions with retroactive effect) as are necessary or appropriate to preserve the intended tax treatment of Awards under the Plan, including, without limitation, any such actions intended to (A) exempt this Plan and/or any Award from the application of Section 409A, and/or (B) comply with the requirements of Section 409A, including, without limitation any such regulations, guidance, compliance programs and other interpretative authority that may be issued after the date of grant of any Award. The Company makes no representations or warranties as to the tax treatment of any Award under Section 409A or otherwise. The Company shall have no obligation under this Section 10(f) or

otherwise to take any action (whether or not described herein) to avoid the imposition of taxes, penalties or interest under Section 409A with respect to any Award and shall have no liability to any Participant or any other person if any Award, compensation or other benefits under the Plan are determined to constitute non-compliant, "nonqualified deferred compensation" subject to the imposition of taxes, penalties and/or interest under Section 409A.

- (ii) Separation from Service. With respect to any Award that constitutes "nonqualified deferred compensation" under Section 409A, any payment or settlement of such Award that is to be made upon a termination of a Participant's Service Provider relationship shall, to the extent necessary to avoid the imposition of taxes under Section 409A, be made only upon the Participant's "separation from service" (within the meaning of Section 409A), whether such "separation from service" occurs upon or subsequent to the termination of the Participant's Service Provider relationship. For purposes of any such provision of this Plan or any Award Agreement relating to any such payments or benefits, references to a "termination," "termination of employment" or like terms shall mean "separation from service."
- (iii) Payments to Specified Employees. Notwithstanding any contrary provision in the Plan or any Award Agreement, any payment(s) of "nonqualified deferred compensation" that are otherwise required to be made under an Award to a "specified employee" (as defined under Section 409A and determined by the Administrator) as a result of his or her "separation from service" shall, to the extent necessary to avoid the imposition of taxes under Code Section 409A(a)(2)(B)(i), be delayed until the expiration of the six-month period immediately following such "separation from service" (or, if earlier, until the date of death of the specified employee) and shall instead be paid (in a manner set forth in the Award agreement) on the day that immediately follows the end of such six-month period or as soon as administratively practicable thereafter (without interest). Any payments of "nonqualified deferred compensation" under such Award that are, by their terms, payable more than six months following the Participant's "separation from service" shall be paid at the time or times such payments are otherwise scheduled to be made.
- (g) Limitations on Liability. Notwithstanding any other provisions of the Plan, no individual acting as a director, officer, other employee or agent of the Company will be liable to any Participant, former Participant, spouse, beneficiary, or any other person for any claim, loss, liability, or expense incurred in connection with the Plan or any Award, nor will such individual be personally liable with respect to the Plan because of any contract or other instrument he or she executes in his or her capacity as an Administrator, director, officer, other employee or agent of the Company. The Company will indemnify and hold harmless each director, officer, other employee and agent of the Company to whom any duty or power relating to the administration or interpretation of the Plan has been or will be granted or delegated, against any cost or expense (including, without limitation, attorneys' fees) or liability (including, without limitation, any sum paid in settlement of a claim with the Administrator's approval) arising out of any act or omission to act concerning this Plan unless arising out of such person's own fraud or bad faith.
- (h) *Lock-Up Period*. The Company may, at the request of any representative of the underwriters or otherwise, in connection with any registration of the offering of any securities of the Company under the Securities Act, prohibit Participants from, directly or indirectly, selling or otherwise transferring any shares of Common Stock or other securities of the Company during a period of up to one hundred eighty days following the effective date of a registration statement of the Company filed under the Securities Act.

- (i) Right of First Refusal.
- (i) Before any shares of Common Stock held by a Participant or any permitted transferee (each, a "*Holder*") may be sold, pledged, assigned, hypothecated, transferred, or otherwise disposed of (each, a "*Transfer*"), the Company or its assignee(s) shall have a right of first refusal to purchase the shares of Common Stock proposed to be Transferred on the terms and conditions set forth in this Section 10(i) (the "*Right of First Refusal*"). In the event that the Company's Articles of Association contain a right of first refusal with respect to the shares of Common Stock, such right of first refusal shall apply to the shares of Common Stock to the extent such provisions are more restrictive on the applicable Participant than the Right of First Refusal set forth in this Section 10(i) and the Right of First Refusal set forth in this Section 10(i) shall not in any way restrict the operation of the Company's Articles of Association.
- (ii) In the event any Holder desires to Transfer any shares of Common Stock, the Holder shall deliver to the Company a written notice (the "Notice") stating: (A) the Holder's bona fide intention to sell or otherwise Transfer such shares of Common Stock; (B) the name of each proposed purchaser or other transferee ("Proposed Transferee"); (C) the number of shares of Common Stock to be Transferred to each Proposed Transferee; and (D) the price for which the Holder proposes to Transfer the shares of Common Stock (the "Offered Price"), and the Holder shall offer such shares of Common Stock at the Offered Price to the Company or its assignee(s).
- (iii) Within fifty days after receipt of the Notice, the Company and/or its assignee(s) may elect in writing to purchase all, but not less than all, of the shares of Common Stock proposed to be Transferred to any one or more of the Proposed Transferees by delivery of a written exercise notice to the Holder (a "Company Notice"). The purchase price ("Purchase Price") for the shares of Common Stock repurchased under this Section 10(i) shall be the Offered Price.
- (iv) Payment of the Purchase Price shall be made, at the option of the Company or its assignee(s), in cash (by check or wire transfer), by cancellation of all or a portion of any outstanding indebtedness of the Holder to the Company (or, in the case of repurchase by an assignee, to the assignee), or by any combination thereof, within five days after delivery of the Company Notice or in the manner and at the times mutually agreed to by the Company and the Holder. Should the Offered Price specified in the Notice be payable in property other than cash, the Company or its assignee shall have the right to pay the purchase price in the form of cash equal in amount to the value of such property, as determined by the Administrator.
- (v) If all or a portion of the shares of Common Stock proposed in the Notice to be Transferred are not purchased by the Company and/or its assignee(s) as provided in this Section 10(i), then the Holder may sell or otherwise Transfer such shares of Common Stock to that Proposed Transferee at the Offered Price or at a higher price; provided that such sale or other Transfer is consummated within sixty days after the date of the Notice; and provided, further, that any such sale or other Transfer is effected in accordance with any Applicable Laws and the Proposed Transferee agrees in writing that the provisions of this Plan and the applicable Award Agreement and any other applicable agreements governing the shares of Common Stock to be Transferred shall continue to apply to the shares of Common Stock in the hands of such Proposed Transferee. If the shares of Common Stock described in the Notice are not Transferred to the Proposed Transferee within such sixty-day period, a new Notice shall be given to the Company, and the Company and/or its assignees shall again be offered the Right of First Refusal, as provided herein, before any shares of Common Stock held by the Holder may be sold or otherwise Transferred.

- (vi) Anything to the contrary contained in this Section 10(i) notwithstanding and to the extent permitted by the Administrator, the Transfer of any or all of the shares of Common Stock during a Participant's lifetime or upon a Participant's death by will or intestacy to the Participant's Immediate Family or a trust for the benefit of the Participant's Immediate Family shall be exempt from the Right of First Refusal. As used herein, "Immediate Family" shall mean spouse, lineal descendant or antecedent, father, mother, brother or sister or stepchild (whether or not adopted). In such case, the transferee or other recipient shall receive and hold the shares of Common Stock so Transferred subject to the provisions of this Plan (including, without limitation, the Right of First Refusal), the applicable Award Agreement and any other applicable agreements governing the shares of Common Stock to be Transferred, and there shall be no further Transfer of such shares of Common Stock except in accordance with the terms of this Section 10(i) (or otherwise as expressly provided under the Plan).
- (vii) The Right of First Refusal shall terminate as to all shares of Common Stock upon the date the Company becomes a Publicly Listed Company.
  - (j) Right to Repurchase Common Stock.
- (i) During the period beginning on the date of a Participant's Termination of Service and ending on the first anniversary of the later of (i) the date of such Termination of Service or (ii) as applicable, the date of the last exercise of any portion of any Options held by the Participant (the "Repurchase Period"), the Company or its assignee(s) (which, for the avoidance of doubt, may include an employee benefit or share trust or similar entity) shall have the option (the "Call Right") to repurchase the Participant's shares of Common Stock (including, without limitation, shares subject to vested Options), provided, however that the Call Right shall terminate upon the Company becoming a Publicly Listed Company. The Call Right may be exercised more than once and for some or all of the shares of Common Stock held by the Participant.
- (ii) The Company and/or its assignee(s) shall exercise the Call Right (if so elected) by written notice to Participant (and/or, if applicable, any permitted transferees) within the Repurchase Period, specifying a date within such period on which the Call Right shall be exercised and the number of shares of Common Stock (including, without limitation, any shares subject to vested Options) as to which the Call Right is being exercised. Upon such notification, the Participant and any permitted transferees shall (A) promptly surrender to the Company and/or its assignee(s), as applicable, any certificates representing the shares of Common Stock being purchased, together with a duly executed repurchase/transfer form for the transfer of such shares of Common Stock to the Company and/or its assignees, as applicable, free and clear of any liens or encumbrances, and (B) forfeit any vested Options with respect to shares of Common Stock subject to repurchase (or the applicable portions thereof). Except as provided below, upon the Company's and/or its assignee(s) receipt of the certificates from the Participant or any permitted transferees and the forfeiture of any applicable vested Options (or portions thereof), the Company and/or its assignee(s) shall deliver to him, her or them payment in cash or by check of the Repurchase Price (as defined below) for the shares of Common Stock being purchased.
  - (iii) The purchase price payable by the Company upon exercise of the Call Right (the "Repurchase Price") shall be as follows:
- (A) In the event of any Termination of Service other than a Termination of Service by the Company for Cause, (i) the Fair Market Value, as of the date the Call Right is being exercised, of the shares of Common Stock with respect to which the Call Right is being exercised, less (ii) if the Call Right is being exercised with respect to shares of Common Stock subject to vested Options, the aggregate exercise price and withholding taxes that would have been payable upon exercise with respect to such shares; and

- (B) In the event of any Termination of Service by the Company for Cause, the lesser of (i) the Fair Market Value, as of the date the Call Right is being exercised, of the shares of Common Stock with respect to which the Call Right is being exercised and (ii) the aggregate purchase price paid for such shares by the Participant.
  - (iv) Notwithstanding anything herein to the contrary, no payment shall be made under this Section that would cause the Company to violate any Applicable Law, or any rights or preference of any preferred shareholders of the Company, any banking agreement or loan or other financial covenant or cause default of any indebtedness of the Company, regardless of when such agreement, covenant or indebtedness was created, incurred or assumed. Any payment under this Section that would cause such violation or default shall result in an extension of the Repurchase Period, in the sole discretion of the Administrator, until such payment shall no longer cause any such violation or default and at which time the Call Right may be exercised.]
- (k) Data Privacy. As a condition of receipt of any Award, each Participant explicitly and unambiguously consents to the collection, use and transfer, in electronic or other form, of personal data as described in this paragraph by and among, as applicable, the Company and its subsidiaries and affiliates for the exclusive purpose of implementing, administering and managing the Participant's participation in the Plan. The Company and its subsidiaries and affiliates may hold certain personal information about a Participant, including but not limited to, the Participant's name, home address and telephone number, date of birth, social security or insurance number or other identification number, salary, nationality, job title(s), any shares held in the Company or any of its subsidiaries and affiliates, details of all Awards, in each case, for the purpose of implementing, managing and administering the Plan and Awards (the "Data"). The Company and its subsidiaries and affiliates may transfer the Data amongst themselves as necessary for the purpose of implementation, administration and management of a Participant's participation in the Plan, and the Company and its subsidiaries and affiliates may each further transfer the Data to any third parties assisting the Company in the implementation, administration and management of the Plan. These recipients may be located in the Participant's country, or elsewhere, and the Participant's country may have different data privacy laws and protections than the recipients' country. Through acceptance of an Award, each Participant authorizes such recipients to receive, possess, use, retain and transfer the Data, in electronic or other form, for the purposes of implementing, administering and managing the Participant's participation in the Plan, including, without limitation, any requisite transfer of such Data as may be required to a broker or other third party with whom the Company or the Participant may elect to deposit any shares of Common Stock. The Data related to a Participant will be held only as long as is necessary to implement, administer, and manage the Participant's participation in the Plan. A Participant may, at any time, view the Data held by the Company with respect to such Participant, request additional information about the storage and processing of the Data with respect to such Participant, recommend any necessary corrections to the Data with respect to the Participant or refuse or withdraw the consents herein in writing, in any case without cost, by contacting his or her local human resources representative. The Company may cancel Participant's ability to participate in the Plan and, in the Administrator's discretion, the Participant may forfeit any outstanding Awards if the Participant refuses or withdraws his or her consents as described herein. For more information on the consequences of refusal to consent or withdrawal of consent, Participants may contact their local human resources representative.
- (l) *Severability*. In the event any portion of the Plan or any action taken pursuant thereto shall be held illegal or invalid for any reason, the illegality or invalidity shall not affect the remaining parts of the Plan, and the Plan shall be construed and enforced as if the illegal or invalid provisions had not been included, and the illegal or invalid action shall be null and void.

- (m) *Governing Documents*. In the event of any contradiction between the Plan and any Award Agreement or any other written agreement between a Participant and the Company or any subsidiary of the Company that has been approved by the Administrator, the terms of the Plan shall govern, unless it is expressly specified in such Award Agreement or other written document that a specific provision of the Plan shall not apply.
- (o) *Governing Law*. The provisions of the Plan and, unless otherwise set forth in the applicable Award Agreement, all Awards made hereunder shall be governed by and interpreted in accordance with the laws of England & Wales, disregarding choice-of-law principles of the law of any jurisdiction that would require the application of the laws of a jurisdiction other than England & Wales.
- (p) Restrictions on Shares; Claw-back Provisions. Shares of Common Stock acquired in respect of Awards shall be subject to such terms and conditions as the Administrator shall determine, including, without limitation, restrictions on the transferability of shares of Common Stock, the right of the Company to repurchase shares of Common Stock, the right of the Company to require that shares of Common Stock be transferred in the event of certain transactions, tag-along rights, bring-along rights, redemption and co-sale rights and voting requirements. Such terms and conditions may be additional to those contained in the Plan and may, as determined by the Administrator, be contained in the applicable Award Agreement or in an exercise notice, or in such other agreement as the Administrator shall determine, in each case in a form determined by the Administrator. The issuance of such shares of Common Stock shall be conditioned on the Participant's consent to such terms and conditions and the Participant's entering into such agreement or agreements. All Awards (including, without limitation, any proceeds, gains or other economic benefit actually or constructively received by Participant upon any receipt or exercise of any Award or upon the receipt or resale of any shares of Common Stock underlying the Award) shall be subject to the provisions of any claw-back policy implemented by the Company to comply with the requirements of applicable law, including, without limitation, the Dodd-Frank Wall Street Reform and Consumer Protection Act and any rules or regulations promulgated thereunder.
- (q) *Titles and Headings*. The titles and headings of the Sections in the Plan are for convenience of reference only and, in the event of any conflict, the text of the Plan, rather than such titles or headings, shall control.
- (r) *Conformity to Securities Laws*. Participant acknowledges that the Plan is intended to conform to the extent necessary with all provisions of securities laws and regulations. Notwithstanding anything herein to the contrary, the Plan and all Awards granted hereunder shall be administered only in such a manner as to conform to such laws, rules and regulations. To the extent permitted by Applicable Laws, the Plan and all Award Agreements shall be deemed amended to the extent necessary to conform to such laws, rules and regulations.
  - 11. Definitions. As used in the Plan, the following words and phrases shall have the following meanings:
- (a) "Administrator" means the Board or a Committee to the extent that the Board's powers or authority under the Plan have been delegated to such Committee.
- (b) "Applicable Laws" means the requirements relating to the administration of equity incentive plans under United Kingdom and U.S. federal and state securities, tax and other applicable laws, rules and regulations, the applicable rules of any stock exchange or quotation system on which the Common Stock is listed or quoted and the applicable laws and rules of any foreign country or other jurisdiction where Awards are granted or issued under the Plan
- (c) "Award" means, individually or collectively, a grant under the Plan of Options, Restricted Stock, Restricted Stock Units or Other Stock-Based Awards.

- (d) "Award Agreement" means a written agreement evidencing an Award, which agreements may be in electronic medium and shall contain such terms and conditions with respect to an Award as the Administrator shall determine, consistent with and subject to the terms and conditions of the Plan.
  - (e) "Board" means the Board of Directors of the Company.
- (f) "Cause," with respect to a Participant, shall include, but not be limited to: (i) the Participant's unauthorized use or disclosure of confidential information or trade secrets of the Company or any material breach of a written agreement between the Participant and the Company, including without limitation a material breach of any employment, confidentiality, non-compete, non-solicit or similar agreement; (ii) the Participant's commission of, indictment for, being found guilty of or the entry of a plea of guilty or nolo contendere by the Participant to, a criminal offence or felony under the laws of the United States or any state thereof or any crime involving dishonesty or moral turpitude (or any similar crime in any jurisdiction outside the United States); (iii) the Participant's negligence or willful misconduct in the performance of the Participant's duties or the Participant's willful or repeated failure or refusal to substantially perform assigned duties; (iv) any act of fraud, embezzlement, material misappropriation or dishonesty committed by the Participant against the Company; or (v) any acts, omissions or statements by the Participant which the Company determines to be (A) materially detrimental or damaging to the reputation, operations, prospects or business relations of the Company or (B) gross misconduct (as determined by the Company).]
  - (g) "Code" means the Internal Revenue Code of 1986, as amended, and the regulations issued thereunder.
- (h) "Committee" means one or more committees or subcommittees of the Board, which may be comprised of one or more directors and/or executive officers of the Company, in either case, to the extent permitted in accordance with Applicable Laws.
  - (i) "Common Stock" means the ordinary shares of the Company having the rights set out in the Company's Articles of Association.
- (j) "Company" means MeiraGTx Limited, a company organized under the laws of the United Kingdom, or any successor thereto. Except where the context otherwise requires, the term "Company" includes any present or future Group Company and any other business venture (including, without limitation, joint venture or limited liability company) in which the Company has a significant interest, as determined by the Administrator.
- (k) "Consultant" means any person, including, without limitation, any advisor, engaged by the Company or a parent or subsidiary of the Company to render services to such entity if: (i) the consultant or adviser renders bona fide services to the Company; (ii) the services rendered by the consultant or advisor are not in connection with the offer or sale of securities in a capital-raising transaction and do not directly or indirectly promote or maintain a market for the Company's securities; and (iii) the consultant or advisor is a natural person, or such other advisor or consultant as is approved by the Administrator
- (l) "*Designated Beneficiary*" means the beneficiary or beneficiaries designated, in a manner determined by the Administrator, by a Participant to receive amounts due or exercise rights of the Participant in the event of the Participant's death or incapacity. In the absence of an effective designation by a Participant, "Designated Beneficiary" shall mean the Participant's estate.

- (m) "Director" means a member of the Board.
- (n) "Disability" means a permanent and total disability within the meaning of Section 22(e)(3) of the Code, as it may be amended from time to time.
- (o) "Dividend Equivalents" means a right granted to a Participant pursuant to Section 6(d)(iii) hereof to receive the equivalent value (in cash or shares of Common Stock) of dividends paid on shares of Common Stock.
- (p) "Employee" means any person, including, without limitation, officers and Directors, employed by the Company or any parent or subsidiary of the Company.
- (q) "*Equity Restructuring*" means, as determined by the Administrator, a non-reciprocal transaction between the Company and its shareholders, such as a share dividend, share split, spin-off or recapitalization through a large, nonrecurring cash dividend, that affects the shares of Common Stock (or other securities of the Company) or the share price of Common Stock (or other securities of the Company) and causes a change in the per share value of the Common Stock underlying outstanding Awards.
  - (r) "Exchange Act" means the Securities Exchange Act of 1934, as amended.
- (s) "Fair Market Value" means, as of any date, the value of Common Stock determined as follows: (i) if the Common Stock is listed on any established stock exchange, its Fair Market Value shall be the closing sales price for such Common Stock as quoted on such exchange for such date, or if no sale occurred on such date, the first market trading day immediately prior to such date during which a sale occurred, as reported in *The Financial Times* or such other source as the Administrator deems reliable; (ii) if the Common Stock is not traded on a stock exchange but is quoted on a national market or other quotation system, the last sales price on such date, or if no sales occurred on such date, then on the date immediately prior to such date on which sales prices are reported, as reported in *The Financial Times* or such other source as the Administrator deems reliable; or (iii) in the absence of an established market for the Common Stock, the Fair Market Value thereof shall be determined by the Administrator in its sole discretion. For purposes of the Plan, Fair Market Value shall be determined without applying any discount for minority ownership or lack of marketability.
- (t) "*Group*" means the Company, any presently existing holding company or undertaking of the Company and any subsidiaries and subsidiary undertakings of the Company or such holding company or undertaking (and the words "subsidiary" and "holding company" shall have the meanings given to them in Section 1159 in the UK Companies Act 2006).
  - (u) "Group Company" means any company in the Group.
  - (v) "Incentive Stock Option" means an "incentive stock option" as defined in Section 422 of the Code.
- (w) "Non-Qualified Stock Option" means an Option that is not intended to be or otherwise does not qualify as an Incentive Stock Option or other form of options that does not provide favorable tax treatment to a Participant.
  - (x) "Option" means an option to purchase Common Stock.

- (y) "Other Stock-Based Awards" means other Awards of shares of Common Stock, and other Awards that are valued in whole or in part by reference to, or are otherwise based on, shares of Common Stock or other property.
  - (z) "Participant" means a Service Provider who has been granted an Award under the Plan.
  - (aa) "Plan" means this 2016 Equity Incentive Plan.
- (bb) "*Publicly Listed Company*" means that the Company or its successor has had any of its shares of Common Stock, or been granted permission for any of its shares of Common Stock to be traded on a recognized investment exchange as defined by Section 285 of the UK Financial Services and Markets Act 2000 (and including, without limitation, the Official List of the London Stock Exchange plc, the New York Stock Exchange and NASDAQ) together with the Alternative Investment Market of the London Stock Exchange plc.
- (cc) "Restricted Stock" means Common Stock awarded to a Participant pursuant to Section 6 hereof that is subject to certain vesting conditions and other restrictions.
- (dd) "*Restricted Stock Unit*" means an unfunded, unsecured right to receive, on the applicable settlement date, one share of Common Stock or an amount in cash or other consideration determined by the Administrator equal to the value thereof as of such payment date, which right may be subject to certain vesting conditions and other restrictions.
- (ee) "Section 409A" means Section 409A of the Code and all regulations, guidance, compliance programs and other interpretative authority thereunder.
  - (ff) "Securities Act" means the Securities Act of 1933, as amended from time to time.
  - (gg) "Service Provider" means an Employee, Consultant or Director.
  - (hh) "Termination of Service" means the date the Participant ceases to be a Service Provider.

# MEIRAGTX LIMITED 2016 EQUITY INCENTIVE PLAN

# US STOCK OPTION AGREEMENT GRANT NOTICE

Unless otherwise defined herein, the terms defined in the MeiraGTx Limited 2016 Equity Incentive Plan (the "Plan") shall have the same defined meanings in this Stock Option Agreement, which includes the terms in this Grant Notice (the "Grant Notice") and Appendix A attached hereto (collectively, the "Agreement").

You have been granted an Option to purchase Common Stock of the Company, subject to the terms and conditions of the Plan and this Agreement, as follows:

Name of Optionee:				
Total Number of Shares Subject to the Option:	[ ]			
Exercise Price per Share:	<b>\$</b> [ ]			
Grant Date:				
Vesting Commencement Date:				
Type of Option:	Incentive Stock Option			
Final Expiration Date:	[ ]1			
Vesting Schedule:	This Option will vest and become exercisable as to 25% of the Shares subject to the Option on the one year anniversary of the Vesting Commencement Date and in 36 substantially equal monthly installments thereafter, subject to the Optionee continuing as a Service Provider through each applicable vesting date.			
Agreement (including this Grant Notice and $\underline{\mathbf{A}}$	reement and understanding that this Option is subject to all of the terms and conditions contained in the <a href="https://www.appendix.A">appendix A</a> attached hereto) and the Plan. ACCORDINGLY, PLEASE BE SURE TO READ ALL OF SPECIFIC TERMS AND CONDITIONS OF THIS OPTION.			
MEIRAGTX LIMITED	OPTIONEE			
By				
Name:	[ ]			
Title:				

Note: The Final Expiration Date will be the 10<sup>th</sup> anniversary of the Grant Date.

#### APPENDIX A TO STOCK OPTION AGREEMENT

#### ARTICLE I.

#### **GRANT OF OPTION**

Section 1.1 Grant of Option. The Company hereby grants to the Optionee the Option to purchase any part or all of an aggregate of the Shares set forth in the Grant Notice to which this Appendix A is attached, upon (and subject to) the terms and conditions set forth in the Plan and this Agreement (including the Grant Notice and this Appendix A). The Optionee hereby agrees that except as required by law, he or she will not disclose to any Person other than the Optionee's spouse and/or tax or financial advisor (if any) the grant of the Option or any of the terms or provisions hereof without the prior approval of the Administrator. The Option shall be an Incentive Stock Option to the maximum extent permitted by law.

Section 1.2 Option Subject to Plan. The Option granted hereunder is subject to the terms and provisions of the Plan.

<u>Section 1.3</u> <u>Exercise Price</u>. The Exercise Price of a Share covered by the Option shall be the Exercise Price per Share as set forth in the Grant Notice (without commission or other charge).

### ARTICLE II.

### **VESTING SCHEDULE; EXERCISABILITY**

- Section 2.1 Vesting and Exercisability of the Option. Subject to Section 2.2 and 2.3, the Option shall become vested and exercisable in such amounts and at such times as are set forth in the vesting schedule in the Grant Notice, except that any Share as to which the Option would be fractionally vested will be accumulated and will vest and become exercisable only when a whole Share has accumulated.
- <u>Section 2.2</u> <u>Discretionary Vesting</u>. The Administrator in its discretion may accelerate the vesting of any portion of the Option that does not otherwise vest pursuant to Section 2.1.
- Section 2.3 No Vesting of Options; Forfeiture. Notwithstanding any other provision to the contrary in this Agreement, unless otherwise determined by the Administrator, any portion of the Option that has not become vested and exercisable on or prior to the date of the Optionee's Termination of Service shall be forfeited on the date of the Optionee's Termination of Service and shall not thereafter become vested or exercisable.
- <u>Section 2.4</u> <u>Exercisability of the Option</u>. The Optionee shall not have the right to exercise the Option until the date the applicable portion of the Option becomes vested. The date that the applicable portion of the Option becomes vested is referred to herein as the "<u>Exercise Commencement Date</u>." Subject to Section 8 of the Plan, following the Exercise Commencement Date, the applicable portion of the Option shall be and shall remain exercisable until it becomes unexercisable under Section 2.5. Once the Option becomes unexercisable, it shall be forfeited immediately.

#### Section 2.5 Expiration of Option.

- (a) The Option may not be exercised to any extent by anyone after the first to occur of the following events:
  - (i) The Final Expiration Date;
- (ii) Except for such longer period of time as the Administrator may otherwise approve, the 90th day following the Optionee's Termination of Service for any reason other than Cause, death or Disability;
  - (iii) Except as the Administrator may otherwise approve, the Optionee's Termination of Service for Cause; or
- (iv) Except for such longer period of time as the Administrator may otherwise approve, 12 months following the Optionee's Termination of Service by reason of the Optionee's death or Disability.
- (b) If the Company has a right to repurchase the Optionee's Option and/or Shares, the Company may exercise such right at any time, regardless of whether the Optionee continues to have a right to exercise the Option under this Section 2.5.
- <u>Section 2.6</u> <u>Partial Exercise</u>. Subject to Section 8 of the Plan, any exercisable portion of the Option or the entire Option, if then wholly exercisable, may be exercised in whole or in part at any time prior to the time when the Option or portion thereof becomes unexercisable.
- Section 2.7 Exercise of Option. The exercise of the Option shall be governed by the terms of this Agreement and the terms of the Plan.
- <u>Section 2.8</u> <u>Manner of Exercise</u>. Unless determined otherwise by the Administrator, as a condition to the exercise of the Option, the Optionee shall notify the Company at least 30 days prior to exercise and no earlier than 90 days prior to exercise that the Optionee intends to exercise. The foregoing sentence shall not apply if the Shares underlying the Option are registered on Form S-8.
- Section 2.9 Special Tax Consequences. The Optionee acknowledges that, to the extent that the aggregate Fair Market Value (determined as of the time the Option is granted) of all Shares with respect to which Incentive Stock Options, including the Option, are first exercisable for the first time by the Optionee in any calendar year exceeds \$100,000 (or such other limitation as imposed by Section 422(d) of the Code), such excess portion of the Option and such other options shall be treated as not qualifying under Section 422 of the Code but rather shall be considered Non-Qualified Stock Options. Participant further acknowledges that the rule set forth in the preceding sentence shall be applied by taking Options and other "incentive stock options" into account in the order in which they were granted.

#### ARTICLE III.

#### **OTHER PROVISIONS**

Section 3.1 Optionee Representation; Not a Contract of Service. The Optionee hereby represents that the Optionee's execution of this Agreement and participation in the Plan is voluntary and that the Optionee has in no way been induced to enter into this Agreement in exchange for or as a requirement of the expectation of service with the Company or any of its parents and subsidiaries. Nothing in this Agreement or in the Plan shall confer upon the Optionee any right to continue as a Service Provider or shall interfere with or restrict in any way the rights of the Company or its parents and subsidiaries, which are hereby expressly reserved, to discharge the Optionee at any time for any reason whatsoever, with or without Cause except pursuant to an employment or consulting agreement executed by and between the Company and the Optionee and approved by the Board.

<u>Section 3.2</u> <u>Shares Subject to Plan</u>. The Optionee acknowledges that this Option and any Shares acquired upon exercise of the Option are subject to the terms of the Plan. In the event of a conflict between the terms of this Agreement and the Plan, the terms of the Plan will control.

Section 3.3 Data Protection. By signing this Agreement, the Optionee acknowledges and agrees that:

- (a) the Company or any of its Affiliates (including the Optionee's employing company) are permitted to hold and process personal (and sensitive) information and data about the Optionee as part of their personnel and other business records and may use such information for the following purposes and to the extent necessary for those purposes:
  - (i) to evaluate the Optionee's performance with the Company or the Optionee's employing company;
  - (ii) to obtain advice on human resource matters from its professional advisers;
  - (iii) to aid the administration of the provision of benefits under employee benefits plans including those provided by third parties;
  - (iv) to aid in the provision of payroll services;
  - (v) to assist the Company and its Affiliates generally in the conduct of their business; and
  - (vi) to comply with any laws and regulations.
- (b) the Company or any of its Affiliates (including the Optionee's employing company) may disclose such information described in (a) above to third parties for the purposes described in (a) above and to the extent necessary for those purposes; and
  - (c) this Section 3.3 applies to any information held, used or disclosed in any medium.

<u>Section 3.4</u> <u>Governing Law and Jurisdiction</u>. This Agreement is governed by and to be construed in accordance with the laws of England and Wales. The Optionee submits to the non-exclusive jurisdiction of the courts of England and Wales as regards any claim, dispute or matter arising out of or in connection with the Agreement and its implementation and effect.

#### ARTICLE IV.

### **DEFINITIONS**

Whenever the following terms are used in this Agreement (including the Grant Notice), they shall have the meaning specified below unless the context clearly indicates to the contrary. Capitalized terms used in this Agreement and not defined below shall have the meaning given such terms in the Plan. The singular pronoun shall include the plural, where the context so indicates.

Section 4.1 Affiliate. "Affiliate" shall mean, with respect to any person, any other person directly or indirectly controlling, controlled by, or under common control with, such person where "control" shall have the meaning given such term under Rule 405 of the Securities Act.

Section 4.2 Exercise Price. "Exercise Price" shall mean the exercise price per Share set forth in the Grant Notice.

- Section 4.3 Final Expiration Date. "Final Expiration Date" shall mean the final expiration date set forth in the Grant Notice.
- Section 4.4 Grant Date. "Grant Date" shall be the grant date set forth in the Grant Notice.
- Section 4.5 Grant Notice" shall mean the Grant Notice referred to in Section 1.1 of this Agreement, which Grant Notice is for all purposes a part of the Agreement.
- Section 4.6 Option. "Option" shall mean the option to purchase Common Stock granted under this Agreement.
- <u>Section 4.7</u> <u>Optionee</u>. "Optionee" shall be the person designated as such in the Grant Notice.
- Section 4.8 Plan. "Plan" shall mean the MeiraGTx Limited 2016 Equity Incentive Plan.
- Section 4.9 Share. "Share" shall mean a share of Common Stock.

\* \* \*

# MEIRAGTX LIMITED 2016 EQUITY INCENTIVE SUB-PLAN

# UK STOCK OPTION AGREEMENT GRANT NOTICE

Unless otherwise defined herein, the terms defined in the MeiraGTx Limited 2016 Equity Incentive Sub-Plan (the "Sub-Plan") shall have the same defined meanings in this UK Stock Option Agreement, which includes the terms in this Grant Notice (the "Grant Notice") and Appendix A attached hereto (collectively, the "Agreement").

You have been granted an Option to purchase Common Stock of the Company, subject to the terms and conditions of the Sub-Plan and this Agreement, as follows:

]

[

Total Number of Shares Subject to the Option:	[	]			
Exercise Price per Share:	\$[	]			
Grant Date:	[	]			
Vesting Commencement Date:	[	]			
Type of Option:	Non-Qualified Stock Option				
Final Expiration Date:	[	]1			
Vesting Schedule:	year anı installm	This Option will vest and become exercisable as to 25% of the Shares subject to the Option on the or year anniversary of the Vesting Commencement Date and in 36 substantially equal monthly installments thereafter, subject to the Optionee continuing as an Employee through each applicable vesting date.			
Your signature below indicates your aga Agreement (including this Grant Notice and APPENDIX A, WHICH CONTAINS THE	<u>Appendix A</u> attach	ned hereto) and th	e Sub-Plan. <b>ACCORD</b> I	INGLY, PLEASE BE SURE T	
MEIRAGTX LIMITED	LIMITED OPTIONEE				
Ву					
Name:			[	]	
Title:					

Name of Optionee:

Note: The Final Expiration Date will be the 10th anniversary of the Grant Date.

#### APPENDIX A TO UK STOCK OPTION AGREEMENT

#### ARTICLE I.

### **GRANT OF OPTION**

Section 1.1 Grant of Option. The Company hereby grants to the Optionee the Option to purchase any part or all of an aggregate of the Shares set forth in the Grant Notice to which this Appendix A is attached, upon (and subject to) the terms and conditions set forth in the Sub-Plan and this Agreement (including the Grant Notice and this Appendix A). The Optionee hereby agrees that except as required by law, he or she will not disclose to any Person other than the Optionee's spouse and/or tax or financial advisor (if any) the grant of the Option or any of the terms or provisions hereof without the prior approval of the Administrator. The Option shall be a Non-Qualified Stock Option to the maximum extent permitted by law.

Section 1.2 Option Subject to Sub-Plan. The Option granted hereunder is subject to the terms and provisions of the Sub-Plan.

<u>Section 1.3</u> <u>Exercise Price</u>. The Exercise Price of a Share covered by the Option shall be the Exercise Price per Share as set forth in the Grant Notice (without commission or other charge).

### ARTICLE II.

### **VESTING SCHEDULE; EXERCISABILITY**

- Section 2.1 Vesting and Exercisability of the Option. Subject to Section 2.2 and 2.3, the Option shall become vested and exercisable in such amounts and at such times as are set forth in the vesting schedule in the Grant Notice, except that any Share as to which the Option would be fractionally vested will be accumulated and will vest and become exercisable only when a whole Share has accumulated.
- <u>Section 2.2</u> <u>Discretionary Vesting</u>. The Administrator in its discretion may accelerate the vesting of any portion of the Option that does not otherwise vest pursuant to Section 2.1.
- Section 2.3 No Vesting of Options; Forfeiture. Notwithstanding any other provision to the contrary in this Agreement, unless otherwise determined by the Administrator, any portion of the Option that has not become vested and exercisable on or prior to the date of the Optionee's Termination of Service shall be forfeited on the date of the Optionee's Termination of Service and shall not thereafter become vested or exercisable.
- Section 2.4 Exercisability of the Option. The Optionee shall not have the right to exercise the Option until the date the applicable portion of the Option becomes vested. The date that the applicable portion of the Option becomes vested is referred to herein as the "Exercise Commencement Date." Subject to Section 2.4(b) below and Section 8 of the Sub-Plan, following the Exercise Commencement Date, the applicable portion of the Option shall be and shall remain exercisable until it becomes unexercisable under Section 2.5. Once the Option becomes unexercisable, it shall be forfeited immediately.

#### Section 2.5 Expiration of Option.

- (a) The Option may not be exercised to any extent by anyone after the first to occur of the following events:
  - (i) The Final Expiration Date;
- (ii) Except for such longer period of time as the Administrator may otherwise approve, the 90th day following the Optionee's Termination of Service for any reason other than Cause, death or Disability;
  - (iii) Except as the Administrator may otherwise approve, the Optionee's Termination of Service for Cause; or
- (iv) Except for such longer period of time as the Administrator may otherwise approve, 12 months following the Optionee's Termination of Service by reason of the Optionee's death or Disability.
- (b) If the Company has a right to repurchase the Optionee's Option and/or Shares, the Company may exercise such right at any time, regardless of whether the Optionee continues to have a right to exercise the Option under this Section 2.5.
- <u>Section 2.6</u> <u>Partial Exercise</u>. Subject to Section 2.4(b) and Section 8 of the Sub-Plan, any exercisable portion of the Option or the entire Option, if then wholly exercisable, may be exercised in whole or in part at any time prior to the time when the Option or portion thereof becomes unexercisable.
- Section 2.7 Exercise of Option. The exercise of the Option shall be governed by the terms of this Agreement and the terms of the Sub-Plan.
- <u>Section 2.8</u> <u>Manner of Exercise</u>. Unless determined otherwise by the Administrator, as a condition to the exercise of the Option, the Optionee shall (i) notify the Company at least 30 days prior to exercise and no earlier than 90 days prior to exercise that the Optionee intends to exercise and (ii) comply with the requirements of Article III. Clause (i) of the foregoing sentence shall not apply if the Shares underlying the Option are registered on Form S-8.

#### ARTICLE III.

#### UK TAX OBLIGATIONS

Section 3.1 Tax Indemnity. The Optionee agrees to indemnify and keep indemnified the Company and his/her employing company ("Employer"), if different, from and against any liability for or obligation to pay any Tax Liability (a "Tax Liability" being any liability for income tax, employee's National Insurance contributions and (at the discretion of the Company) Employer's National Insurance contributions that is attributable to (1) the grant or exercise of, or any benefit derived by the Optionee from, the Option; (2) the acquisition by the Optionee of the Shares on exercise of the Options and any benefit derived by the Optionee from the Shares; (3) any restrictions applicable to any Shares held by the Optionee ceasing to apply to those Shares; or (4) the disposal of any Shares (each of those events referred to as a "Taxable Event")).

Section 3.2 <u>Joint Election</u>. At the discretion of the Company, the Option cannot be exercised until the Optionee has entered into an election with the Company (or his/her Employer) (as appropriate) in a form approved by the Company and Her Majesty's Revenue & Customs under which any liability of the Company and/or the Employer for Employer's National Insurance contributions arising in respect of the granting, vesting, exercise of or other dealing in the Option, or the acquisition of Shares on exercise of the Option, is transferred to and met by the Optionee.

<u>Section 3.3</u> <u>Tax Liability</u>. The Option cannot be exercised until the Optionee has made such arrangements as the Company and his/her Employer may require for the satisfaction of any Tax Liability that may arise in connection with the exercise of the Option and/or the acquisition of the Shares by the Optionee. The Company shall not be required to issue, allot or transfer Shares until the Optionee has satisfied this obligation.

Section 3.4 Election. The Optionee undertakes that, upon request by the Company, he/she will join with his/her Employer in electing, pursuant to Section 431 of the Income Tax (Earnings and Pensions) Act 2003 ("ITEPA") that, for relevant tax purposes, the market value of the Shares acquired on exercise of the Option, on any occasion will be calculated as if the Shares were not restricted and Sections 425 to 430 (inclusive) of ITEPA are not to apply to such Shares.

Section 3.5 Loan. The Optionee agrees that if the Optionee does not pay his/her Employer or the Company does not withhold from the Optionee the full amount of any Tax Liability within ninety (90) days after the end of the tax year in which the Taxable Event occurred, or such other period specified in Section 222(1)(c) of ITEPA, then the amount that should have been withheld shall constitute a loan owed by the Optionee to the Employer, effective 90 days after the end of the tax year in which the Taxable Event occurred. The Optionee agrees that the loan will bear interest at the official rate of HMRC and will be immediately due and repayable by the Optionee, and the Company and/or the Employer may recover it at any time thereafter by: (i) withholding the funds from salary, bonus or any other funds due to the Optionee by the Company or the Employer; (ii) withholding the Shares issued upon vesting and exercise of the Option or from the cash proceeds from the sale of Shares; or (iii) demanding cash or a cheque from the Optionee. The Optionee also authorizes the Company to delay the issuance of any Shares to the Optionee unless and until the loan is repaid in full.

### ARTICLE IV.

### **OTHER PROVISIONS**

Section 4.1 Optionee Representation; Not a Contract of Employment. The Optionee hereby represents that the Optionee's execution of this Agreement and participation in the Sub-Plan is voluntary and that the Optionee has in no way been induced to enter into this Agreement in exchange for or as a requirement of the expectation of employment with the Company or any of its parents and subsidiaries. Nothing in this Agreement or in the Sub-Plan shall confer upon the Optionee any right to continue as an Employee or shall interfere with or restrict in any way the rights of the Company or its parents and subsidiaries, which are hereby expressly reserved, to discharge the Optionee at any time for any reason whatsoever, with or without Cause except pursuant to an employment agreement executed by and between the Company and the Optionee and approved by the Board. Neither the Sub-Plan nor the Agreement afford the Optionee any rights to compensation or damages including for loss or potential loss that the Optionee may suffer by reason of being unable to exercise the Option as a result of the termination of the Sub-Plan, lapse of the Option or the termination of the Optionee's employment.

<u>Section 4.2</u> <u>Shares Subject to Sub-Plan</u>. The Optionee acknowledges that this Option and any Shares acquired upon exercise of the Option are subject to the terms of the Sub-Plan. In the event of a conflict between the terms of this Agreement and the Sub-Plan, the terms of the Sub-Plan will control.

#### Section 4.3 Data Protection. By signing this Agreement, the Optionee acknowledges and agrees that:

- (a) the Company or any of its Affiliates (including the Employer) are permitted to hold and process personal (and sensitive) information and data about the Optionee as part of their personnel and other business records and may use such information for the following purposes and to the extent necessary for those purposes:
  - (i) to evaluate the Optionee's performance with the Company or Employer;
  - (ii) to obtain advice on human resource matters from its professional advisers;
  - (iii) to aid the administration of the provision of benefits under employee benefits plans including those provided by third parties;
  - (iv) to aid in the provision of payroll services;
  - (v) to assist the Company and its Affiliates generally in the conduct of their business; and
  - (vi) to comply with any laws and regulations.
- (b) the Company or any of its Affiliates (including the Employer) may disclose such information described in (a) above to third parties for the purposes described in (a) above and to the extent necessary for those purposes; and
  - (c) this Section 4.3 applies to any information held, used or disclosed in any medium.

<u>Section 4.4</u> <u>Governing Law and Jurisdiction</u>. This Agreement is governed by and to be construed in accordance with the laws of England and Wales. The Optionee submits to the non-exclusive jurisdiction of the courts of England and Wales as regards any claim, dispute or matter arising out of or in connection with the Agreement and its implementation and effect.

# ARTICLE V. DEFINITIONS

Whenever the following terms are used in this Agreement (including the Grant Notice), they shall have the meaning specified below unless the context clearly indicates to the contrary. Capitalized terms used in this Agreement and not defined below shall have the meaning given such terms in the Sub-Plan. The singular pronoun shall include the plural, where the context so indicates.

- Section 5.1 Affiliate. "Affiliate" shall mean, with respect to any person, any other person directly or indirectly controlling, controlled by, or under common control with, such person where "control" shall have the meaning given such term under Rule 405 of the Securities Act.
- Section 5.2 Exercise Price. "Exercise Price" shall mean the exercise price per Share set forth in the Grant Notice.
- Section 5.3 Final Expiration Date. "Final Expiration Date" shall mean the final expiration date set forth in the Grant Notice.
- Section 5.4 Grant Date. "Grant Date" shall be the grant date set forth in the Grant Notice.
- Section 5.5 Grant Notice" shall mean the Grant Notice referred to in Section 1.1 of this Agreement, which Grant Notice is for all purposes a part of the Agreement.

Section 5.6 Option. "Option" shall mean the option to purchase Common Stock granted under this Agreement.

<u>Section 5.7</u> <u>Optionee</u>. "Optionee" shall be the Person designated as such in the Grant Notice.

Section 5.8 Share. "Share" shall mean a share of Common Stock.

Section 5.9 Sub-Plan. "Sub-Plan" shall mean the MeiraGTx Limited 2016 Equity Incentive Sub-Plan.

\* \* \*

### MEIRAGTX HOLDINGS PLC 2018 INCENTIVE AWARD PLAN

## ARTICLE I. PURPOSE

The Plan's purpose is to enhance the Company's ability to attract, retain and motivate persons who make (or are expected to make) important contributions to the Company by providing these individuals with equity ownership opportunities. Capitalized terms used in the Plan are defined in Article XI.

### ARTICLE II. ELIGIBILITY

Service Providers are eligible to be granted Awards under the Plan, subject to the limitations described herein.

# ARTICLE III. ADMINISTRATION AND DELEGATION

- 3.1 <u>Administration</u>. The Plan is administered by the Administrator. The Administrator has authority to determine which Service Providers receive Awards, grant Awards and set Award terms and conditions, subject to the conditions and limitations in the Plan. The Administrator also has the authority to take all actions and make all determinations under the Plan, to interpret the Plan and Award Agreements and to adopt, amend and repeal Plan administrative rules, guidelines and practices as it deems advisable. The Administrator may correct defects and ambiguities, supply omissions and reconcile inconsistencies in the Plan or any Award as it deems necessary or appropriate to administer the Plan and any Awards. The Administrator's determinations under the Plan are in its sole discretion and will be final and binding on all persons having or claiming any interest in the Plan or any Award.
- 3.2 <u>Appointment of Committees</u>. To the extent Applicable Laws permit, the Board may delegate any or all of its powers under the Plan to one or more Committees or officers of the Company or any of its Subsidiaries. The Board may abolish any Committee or re-vest in itself any previously delegated authority at any time.

# ARTICLE IV. SHARES AVAILABLE FOR AWARDS

- 4.1 <u>Number of Shares</u>. Subject to adjustment under Article VIII and the terms of this Article IV, Awards may be made under the Plan covering up to the Overall Share Limit. As of the Plan's effective date under Section 10.3, the Company will cease granting awards under the Prior Plans; however, Prior Plan Awards will remain subject to the terms of the applicable Prior Plan. Shares issued under the Plan may consist of authorized but unissued Shares, Shares purchased on the open market or treasury Shares.
- 4.2 <u>Share Recycling</u>. If all or any part of an Award or Prior Plan Award expires, lapses or is terminated, exchanged for cash, surrendered, repurchased, canceled without having been fully exercised or forfeited, in any case, in a manner that results in the Company acquiring Shares covered by the Award or Prior Plan Award at a price not greater than the price (as adjusted to reflect any Equity Restructuring)

paid by the Participant for such Shares or not issuing any Shares covered by the Award or Prior Plan Award, the unused Shares covered by the Award or Prior Plan Award will, as applicable, become or again be available for Award grants under the Plan. Further, Shares delivered (either by actual delivery or attestation) to the Company by a Participant to satisfy the applicable exercise or purchase price of an Award or Prior Plan Award and/or to satisfy any applicable tax withholding obligation (including Shares retained by the Company from the Award or Prior Plan Award being exercised or purchased and/or creating the tax obligation) will, as applicable, become or again be available for Award grants under the Plan. The payment of Dividend Equivalents in cash in conjunction with any outstanding Awards or Prior Plan Awards shall not count against the Overall Share Limit.

- 4.3 <u>Incentive Stock Option Limitations</u>. Notwithstanding anything to the contrary herein, no more than 16,547,897 Shares may be issued pursuant to the exercise of Incentive Stock Options.
- 4.4 <u>Substitute Awards</u>. In connection with an entity's merger or consolidation with the Company or the Company's acquisition of an entity's property or stock, the Administrator may grant Awards in substitution for any options or other stock or stock-based awards granted before such merger or consolidation by such entity or its affiliate. Substitute Awards may be granted on such terms as the Administrator deems appropriate, notwithstanding limitations on Awards in the Plan. Substitute Awards will not count against the Overall Share Limit (nor shall Shares subject to a Substitute Award be added to the Shares available for Awards under the Plan as provided above), except that Shares acquired by exercise of substitute Incentive Stock Options will count against the maximum number of Shares that may be issued pursuant to the exercise of Incentive Stock Options under the Plan. Additionally, in the event that a company acquired by the Company or any Subsidiary or with which the Company or any Subsidiary combines has shares available under a pre-existing plan approved by shareholders and not adopted in contemplation of such acquisition or combination, the shares available for grant pursuant to the terms of such pre-existing plan (as adjusted, to the extent appropriate, using the exchange ratio or other adjustment or valuation ratio or formula used in such acquisition or combination to determine the consideration payable to the holders of common stock of the entities party to such acquisition or combination) may be used for Awards under the Plan and shall not reduce the Shares authorized for grant under the Plan (and Shares subject to such Awards shall not be added to the Shares available for Awards under the Plan as provided above); provided that Awards using such available shares shall not be made after the date awards or grants could have been made under the terms of the pre-existing plan, absent the acquisition or combination, and shall only be made to individuals who were not Employees or Directors prior to such ac
- 4.5 <u>Non-Employee Director Compensation</u>. Notwithstanding any provision to the contrary in the Plan, the Administrator may establish compensation for non-employee Directors from time to time, subject to the limitations in the Plan. The Administrator will from time to time determine the terms, conditions and amounts of all such non-employee Director compensation in its discretion and pursuant to the exercise of its business judgment, taking into account such factors, circumstances and considerations as it shall deem relevant from time to time.

# ARTICLE V. OPTIONS AND SHARE APPRECIATION RIGHTS

5.1 <u>General</u>. The Administrator may grant Options or Share Appreciation Rights to Service Providers subject to the limitations in the Plan, including any limitations in the Plan that apply to Incentive Stock Options. The Administrator will determine the number of Shares covered by each Option and Share Appreciation Right, the exercise price of each Option and Share Appreciation Right and the conditions and limitations applicable to the exercise of each Option and Share Appreciation Right. A Share Appreciation Right will entitle the Participant (or other person entitled to exercise the Share

Appreciation Right) to receive from the Company upon exercise of the exercisable portion of the Share Appreciation Right an amount determined by multiplying the excess, if any, of the Fair Market Value of one Share on the date of exercise over the exercise price per Share of the Share Appreciation Right by the number of Shares with respect to which the Share Appreciation Right is exercised, subject to any limitations of the Plan or that the Administrator may impose and payable in cash, Shares valued at Fair Market Value or a combination of the two as the Administrator may determine or provide in the Award Agreement.

- 5.2 Exercise Price. The Administrator will establish each Option's and Share Appreciation Right's exercise price and specify the exercise price in the Award Agreement. The exercise price will not be less than 100% of the Fair Market Value on the grant date of the Option or Share Appreciation Right.
- 5.3 <u>Duration</u>. Each Option or Share Appreciation Right will be exercisable at such times and as specified in the Award Agreement, provided that the term of an Option or Share Appreciation Right will not exceed ten years. Notwithstanding the foregoing and unless determined otherwise by the Company, in the event that on the last business day of the term of an Option or Share Appreciation Right (other than an Incentive Stock Option) (i) the exercise of the Option or Share Appreciation Right is prohibited by Applicable Law, as determined by the Company, or (ii) Shares may not be purchased or sold by the applicable Participant due to any Company insider trading policy (including blackout periods) or a "lock-up" agreement undertaken in connection with an issuance of securities by the Company, the term of the Option or Share Appreciation Right shall be extended until the date that is thirty (30) days after the end of the legal prohibition, black-out period or lock-up agreement, as determined by the Company; provided, however, in no event shall the extension last beyond the ten year term of the applicable Option or Share Appreciation Right. Notwithstanding the foregoing, if the Participant, prior to the end of the term of an Option or Share Appreciation Right, violates the non-competition, non-solicitation, confidentiality or other similar restrictive covenant provisions of any employment contract, confidentiality and nondisclosure agreement or other agreement between the Participant and the Company or any of its Subsidiaries, the right of the Participant and the Participant's transferees to exercise any Option or Share Appreciation Right issued to the Participant shall terminate immediately upon such violation, unless the Company otherwise determines. In addition, if, prior to the end of the term of an Option or Share Appreciation Right, the Participant is given notice by the Company or any of its Subsidiaries of the Participant's Termination of Service by the Company or any of its Subsidiaries for Cause, and the effective date of such Termination of Service is subsequent to the date of the delivery of such notice, the right of the Participant and the Participant's transferees to exercise any Option or Share Appreciation Right issued to the Participant shall be suspended from the time of the delivery of such notice until the earlier of (i) such time as it is determined or otherwise agreed that the Participant's service as a Service Provider will not be terminated for Cause as provided in such notice or (ii) the effective date of the Participant's Termination of Service by the Company or any of its Subsidiaries for Cause (in which case the right of the Participant and the Participant's transferees to exercise any Option or Share Appreciation Right issued to the Participant will terminate immediately upon the effective date of such termination of Service).
- 5.4 Exercise. Options and Share Appreciation Rights may be exercised by delivering to the Company a written notice of exercise, in a form the Administrator approves (which may be electronic), signed by the person authorized to exercise the Option or Share Appreciation Right, together with, as applicable, payment in full (i) as specified in Section 5.5 for the number of Shares for which the Award is exercised and (ii) as specified in Section 9.5 for any applicable taxes. Unless the Administrator otherwise determines, an Option or Share Appreciation Right may not be exercised for a fraction of a Share.

- 5.5 <u>Payment Upon Exercise</u>. Subject to Section 10.8, any Company insider trading policy (including blackout periods) and Applicable Laws, the exercise price of an Option must be paid by:
- (a) cash, wire transfer of immediately available funds or by check payable to the order of the Company, provided that the Company may limit the use of one of the foregoing payment forms if one or more of the payment forms below is permitted;
- (b) if there is a public market for Shares at the time of exercise, unless the Company otherwise determines, (A) delivery (including telephonically to the extent permitted by the Company) of an irrevocable and unconditional undertaking by a broker acceptable to the Company to deliver promptly to the Company sufficient funds to pay the exercise price, or (B) the Participant's delivery to the Company of a copy of irrevocable and unconditional instructions to a broker acceptable to the Company to deliver promptly to the Company cash or a check sufficient to pay the exercise price; provided that such amount is paid to the Company at such time as may be required by the Administrator;
- (c) to the extent permitted by the Administrator, delivery (either by actual delivery or attestation) of Shares owned by the Participant valued at their Fair Market Value;
- (d) to the extent permitted by the Administrator, surrendering Shares then issuable upon the Option's exercise valued at their Fair Market Value on the exercise date;
- (e) to the extent permitted by the Administrator, delivery of a promissory note or any other property that the Administrator determines is good and valuable consideration; or
  - (f) to the extent permitted by the Company, any combination of the above payment forms approved by the Administrator.

# ARTICLE VI. RESTRICTED SHARES; RESTRICTED SHARE UNITS

6.1 General. The Administrator may grant Restricted Shares, or the right to purchase Restricted Shares, to any Service Provider, subject to the Company's right to repurchase all or part of such shares at their issue price or other stated or formula price from the Participant (or to require forfeiture of such shares) if conditions the Administrator specifies in the Award Agreement are not satisfied before the end of the applicable restriction period or periods that the Administrator establishes for such Award. In addition, the Administrator may grant to Service Providers Restricted Share Units, which may be subject to vesting and forfeiture conditions during the applicable restriction period or periods, as set forth in an Award Agreement. The Administrator will determine and set forth in the Award Agreement the terms and conditions for each Restricted Shares and Restricted Share Unit Award, subject to the conditions and limitations contained in the Plan.

#### 6.2 Restricted Shares.

(a) <u>Dividends</u>. Participants holding Restricted Shares will be entitled to all ordinary cash dividends paid with respect to such Shares, unless the Administrator provides otherwise in the Award Agreement. In addition, unless the Administrator provides otherwise, if any dividends or distributions are paid in Shares, or consist of a dividend or distribution to holders of Ordinary Shares of property other than an ordinary cash dividend, the Shares or other property will be subject to the same restrictions on transferability and forfeitability as the Restricted Shares with respect to which they were paid.

(b) <u>Share Certificates</u>. The Company may require that the Participant deposit in escrow with the Company (or its designee) any share certificates issued in respect of the Restricted Shares, together with a form of proxy and form of transfer endorsed in blank.

#### 6.3 Restricted Share Units.

- (a) <u>Settlement</u>. The Administrator may provide that settlement of Restricted Share Units will occur upon or as soon as reasonably practicable after the Restricted Share Units vest or will instead be deferred, on a mandatory basis or at the Participant's election, in a manner intended to comply with Section 409A.
- (b) <u>Shareholder Rights</u>. A Participant will have no rights of a shareholder with respect to Shares subject to any Restricted Share Unit unless and until the Shares are delivered in settlement of the Restricted Share Unit.
- (c) <u>Dividend Equivalents</u>. If the Administrator provides, a grant of Restricted Share Units may provide a Participant with the right to receive Dividend Equivalents. Dividend Equivalents may be paid currently or credited to an account for the Participant, settled in cash or Shares and subject to the same restrictions on transferability and forfeitability as the Restricted Share Units with respect to which the Dividend Equivalents are granted and subject to other terms and conditions as set forth in the Award Agreement.

# ARTICLE VII. OTHER SHARE OR CASH BASED AWARDS

Other Share or Cash Based Awards may be granted to Participants, including Awards entitling Participants to receive Shares to be delivered in the future and including annual or other periodic or long-term cash bonus awards (whether based on specified Performance Criteria or otherwise), in each case subject to any conditions and limitations in the Plan. Such Other Share or Cash Based Awards will also be available as a payment form in the settlement of other Awards, as standalone payments and as payment in lieu of compensation to which a Participant is otherwise entitled. Other Share or Cash Based Awards may be paid in Shares, cash or other property, as the Administrator determines. Subject to the provisions of the Plan, the Administrator will determine the terms and conditions of each Other Share or Cash Based Award, including any purchase price, performance goal (which may be based on the Performance Criteria), transfer restrictions, and vesting conditions, which will be set forth in the applicable Award Agreement.

# ARTICLE VIII. ADJUSTMENTS FOR CHANGES IN ORDINARY SHARES AND CERTAIN OTHER EVENTS

8.1 <u>Equity Restructuring</u>. In connection with any Equity Restructuring, notwithstanding anything to the contrary in this Article VIII, the Administrator will equitably adjust each outstanding Award as it deems appropriate to reflect the Equity Restructuring, which may include adjusting the number and type of securities subject to each outstanding Award and/or the Award's exercise price or grant price (if applicable), granting new Awards to Participants, and making a cash payment to Participants. The adjustments provided under this Section 8.1 will be nondiscretionary and final and binding on the affected Participant and the Company; provided that the Administrator will determine whether an adjustment is equitable.

8.2 <u>Corporate Transactions</u>. In the event of any dividend or other distribution (whether in the form of cash, Ordinary Shares, other securities, or other property), reorganization, merger, consolidation, combination, amalgamation, repurchase, recapitalization, liquidation, dissolution, or sale, transfer, exchange or other disposition of all or substantially all of the assets of the Company, or sale or exchange of Ordinary Shares or other securities of the Company, Change in Control, issuance of warrants or other

rights to purchase Ordinary Shares or other securities of the Company, other similar corporate transaction or event, other unusual or nonrecurring transaction or event affecting the Company or its financial statements or any change in any Applicable Laws or accounting principles, the Administrator, on such terms and conditions as it deems appropriate, either by the terms of the Award or by action taken prior to the occurrence of such transaction or event (except that action to give effect to a change in Applicable Law or accounting principles may be made within a reasonable period of time after such change) and either automatically or upon the Participant's request, is hereby authorized to take any one or more of the following actions whenever the Administrator determines that such action is appropriate in order to (x) prevent dilution or enlargement of the benefits or potential benefits intended by the Company to be made available under the Plan or with respect to any Award granted or issued under the Plan, (y) to facilitate such transaction or event or (z) give effect to such changes in Applicable Laws or accounting principles:

- (a) To provide for the cancellation of any such Award in exchange for either an amount of cash or other property with a value equal to the amount that could have been obtained upon the exercise or settlement of the vested portion of such Award or realization of the Participant's rights under the vested portion of such Award, as applicable; provided that, if the amount that could have been obtained upon the exercise or settlement of the vested portion of such Award or realization of the Participant's rights, in any case, is equal to or less than zero, then the Award may be terminated without payment;
- (b) To provide that such Award shall vest and, to the extent applicable, be exercisable as to all shares covered thereby, notwithstanding anything to the contrary in the Plan or the provisions of such Award;
- (c) To provide that such Award be assumed by the successor or survivor corporation, or a parent or subsidiary thereof, or shall be substituted for by awards covering the stock of the successor or survivor corporation, or a parent or subsidiary thereof, with appropriate adjustments as to the number and kind of shares and/or applicable exercise or purchase price, in all cases, as determined by the Administrator;
- (d) To make adjustments in the number and type of Ordinary Shares (or other securities or property) subject to outstanding Awards and/or with respect to which Awards may be granted under the Plan (including, but not limited to, adjustments of the limitations in Article IV hereof on the maximum number and kind of shares which may be issued) and/or in the terms and conditions of (including the grant or exercise price), and the criteria included in, outstanding Awards;
  - (e) To replace such Award with other rights or property selected by the Administrator; and/or
  - (f) To provide that the Award will terminate and cannot vest, be exercised or become payable after the applicable event.
- 8.3 <u>Administrative Stand Still</u>. In the event of any pending share dividend, share split, combination or exchange of shares, merger, consolidation or other distribution (other than normal cash dividends) of Company assets to shareholders, or any other extraordinary transaction or change affecting the Shares or the share price of Ordinary Shares, including any Equity Restructuring or any securities offering or other similar transaction, for administrative convenience, the Administrator may refuse to permit the exercise of any Award for up to sixty days before or after such transaction.

8.4 General. Except as expressly provided in the Plan or the Administrator's action under the Plan, no Participant will have any rights due to any subdivision or consolidation of Shares of any class, dividend payment, increase or decrease in the number of Shares of any class or dissolution, liquidation, merger, or consolidation of the Company or other corporation. Except as expressly provided with respect to an Equity Restructuring under Section 8.1 above or the Administrator's action under the Plan, no issuance by the Company of Shares of any class, or securities convertible into Shares of any class, will affect, and no adjustment will be made regarding, the number of Shares subject to an Award or the Award's grant or exercise price. The existence of the Plan, any Award Agreements and the Awards granted hereunder will not affect or restrict in any way the Company's right or power to make or authorize (i) any adjustment, recapitalization, reorganization or other change in the Company's capital structure or its business, (ii) any merger, consolidation, dissolution or liquidation of the Company or sale of Company assets or (iii) any sale or issuance of securities, including securities with rights superior to those of the Shares or securities convertible into or exchangeable for Shares. The Administrator may treat Participants and Awards (or portions thereof) differently under this Article VIII.

# ARTICLE IX. GENERAL PROVISIONS APPLICABLE TO AWARDS

- 9.1 <u>Transferability</u>. Except as the Administrator may determine or provide in an Award Agreement or otherwise for Awards other than Incentive Stock Options, Awards may not be sold, assigned, transferred, pledged or otherwise encumbered, either voluntarily or by operation of law, except by will or the laws of descent and distribution, or, subject to the Administrator's consent, pursuant to a domestic relations order, and, during the life of the Participant, will be exercisable only by the Participant. References to a Participant, to the extent relevant in the context, will include references to a Participant's authorized transferee that the Administrator specifically approves.
- 9.2 <u>Documentation</u>. Each Award will be evidenced in an Award Agreement, which may be written or electronic, as the Administrator determines. Each Award may contain terms and conditions in addition to those set forth in the Plan.
- 9.3 <u>Discretion</u>. Except as the Plan otherwise provides, each Award may be made alone or in addition or in relation to any other Award. The terms of each Award to a Participant need not be identical, and the Administrator need not treat Participants or Awards (or portions thereof) uniformly.
- 9.4 <u>Termination of Status</u>. The Administrator will determine how the disability, death, retirement, authorized leave of absence or any other change or purported change in a Participant's Service Provider status affects an Award and the extent to which, and the period during which, the Participant, the Participant's legal representative, conservator, guardian or Designated Beneficiary may exercise rights under the Award, if applicable.
- 9.5 <u>Withholding</u>. Each Participant must pay the Company, or make provision satisfactory to the Administrator for payment of, any taxes required by law to be withheld in connection with such Participant's Awards by the date of the event creating the tax liability. The Company may deduct an amount sufficient to satisfy such tax obligations based on the applicable statutory withholding rates (or such other rate as may be determined by the Company after considering any accounting consequences or costs) from any payment of any kind otherwise due to a Participant. Subject to Section 10.8 and any

Company insider trading policy (including blackout periods), Participants may satisfy such tax obligations (i) in cash, by wire transfer of immediately available funds, by check made payable to the order of the Company, provided that the Company may limit the use of the foregoing payment forms if one or more of the payment forms below is permitted, (ii) to the extent permitted by the Administrator, in whole or in part by delivery of Shares, including Shares retained from the Award creating the tax obligation, valued at their Fair Market Value, (iii) if there is a public market for Shares at the time the tax obligations are satisfied, unless the Company otherwise determines, (A) delivery (including telephonically to the extent permitted by the Company) of an irrevocable and unconditional undertaking by a broker acceptable to the Company to deliver promptly to the Company sufficient funds to satisfy the tax obligations, or (B) delivery by the Participant to the Company of a copy of irrevocable and unconditional instructions to a broker acceptable to the Company to deliver promptly to the Company cash or a check sufficient to satisfy the tax withholding; provided that such amount is paid to the Company at such time as may be required by the Administrator, or (iv) to the extent permitted by the Company, any combination of the foregoing payment forms approved by the Administrator. If any tax withholding obligation will be satisfied under clause (ii) of the immediately preceding sentence by the Company's retention of Shares from the Award creating the tax obligation and there is a public market for Shares at the time the tax obligation is satisfied, the Company may elect to instruct any brokerage firm determined acceptable to the Company for such purpose to sell on the applicable Participant's behalf some or all of the Shares retained and to remit the proceeds of the sale to the Company or its designee, and each Participant's acceptance of an Award under the Plan will constitute the Participant's authorization to the

9.6 Amendment of Award; Repricing. The Administrator may amend, modify or terminate any outstanding Award, including by substituting another Award of the same or a different type, changing the exercise or settlement date, and converting an Incentive Stock Option to a Non-Qualified Stock Option. The Participant's consent to such action will be required unless (i) the action, taking into account any related action, does not materially and adversely affect the Participant's rights under the Award, or (ii) the change is permitted under Article VIII or pursuant to Section 10.6. Notwithstanding the foregoing or anything in the Plan to the contrary, the Administrator may not except pursuant to Article VIII, without the approval of the shareholders of the Company, reduce the exercise price per share of outstanding Options or Share Appreciation Rights or cancel outstanding Options or Share Appreciation Rights with an exercise price per share that is less than the exercise price per share of the original Options or Share Appreciation Rights.

9.7 <u>Conditions on Delivery of Shares</u>. The Company will not be obligated to deliver any Shares under the Plan or remove restrictions from Shares previously delivered under the Plan until (i) all Award conditions have been met or removed to the Company's satisfaction, (ii) as determined by the Company, all other legal matters regarding the issuance and delivery of such Shares have been satisfied, including any applicable securities laws and stock exchange or stock market rules and regulations, and (iii) the Participant has executed and delivered to the Company such representations or agreements as the Administrator deems necessary or appropriate to satisfy any Applicable Laws. The Company's inability to obtain authority from any regulatory body having jurisdiction, which the Administrator determines is necessary to the lawful issuance and sale of any securities, will relieve the Company of any liability for failing to issue or sell such Shares as to which such requisite authority has not been obtained.

9.8 <u>Acceleration</u>. The Administrator may at any time provide that any Award will become immediately vested and fully or partially exercisable, free of some or all restrictions or conditions, or otherwise fully or partially realizable.

9.9 Additional Terms of Incentive Stock Options. The Administrator may grant Incentive Stock Options only to employees of the Company, any of its present or future parent or subsidiary corporations, as defined in Sections 424(e) or (f) of the Code, respectively, and any other entities the employees of which are eligible to receive Incentive Stock Options under the Code. If an Incentive Stock Option is granted to a Greater Than 10% Shareholder, the exercise price will not be less than 110% of the Fair Market Value on the Option's grant date, and the term of the Option will not exceed five years. All Incentive Stock Options will be subject to and construed consistently with Section 422 of the Code. By accepting an Incentive Stock Option, the Participant agrees to give prompt notice to the Company of dispositions or other transfers (other than in connection with a Change in Control) of Shares acquired under the Option made within (i) two years from the grant date of the Option or (ii) one year after the transfer of such Shares to the Participant, specifying the date of the disposition or other transfer and the amount the Participant realized, in cash, other property, assumption of indebtedness or other consideration, in such disposition or other transfer. Neither the Company nor the Administrator will be liable to a Participant, or any other party, if an Incentive Stock Option fails or ceases to qualify as an "incentive stock option" under Section 422 of the Code. Any Incentive Stock Option or portion thereof that fails to qualify as an "incentive stock option" under Section 422 of the Code for any reason, including becoming exercisable with respect to Shares having a fair market value exceeding the \$100,000 limitation under Treasury Regulation Section 1.422-4, will be a Non-Qualified Stock Option.

# ARTICLE X. MISCELLANEOUS

- 10.1 No Right to Employment or Other Status. No person will have any claim or right to be granted an Award, and the grant of an Award will not be construed as giving a Participant the right to continued employment or any other relationship with the Company. The Company expressly reserves the right at any time to dismiss or otherwise terminate its relationship with a Participant free from any liability or claim under the Plan or any Award, except as expressly provided in an Award Agreement.
- 10.2 No Rights as Shareholder; Certificates. Subject to the Award Agreement, no Participant or Designated Beneficiary will have any rights as a shareholder with respect to any Shares to be distributed under an Award until becoming the record holder of such Shares. Notwithstanding any other provision of the Plan, unless the Administrator otherwise determines or Applicable Laws require, the Company will not be required to deliver to any Participant certificates evidencing Shares issued in connection with any Award and instead such Shares may be recorded in the books of the Company (or, as applicable, its transfer agent or share plan administrator). The Company may place legends on share certificates issued under the Plan that the Administrator deems necessary or appropriate to comply with Applicable Laws.
- 10.3 Effective Date and Term of Plan. Unless earlier terminated by the Board, the Plan will become effective on the day prior to the Public Trading Date and will remain in effect until the tenth anniversary of the earlier of (i) the date the Board adopted the Plan or (ii) the date the Company's shareholders approved the Plan, but Awards previously granted may extend beyond that date in accordance with the Plan. If the Plan is not approved by the Company's shareholders, the Plan will not become effective, no Awards will be granted under the Plan and the Prior Plans will continue in full force and effect in accordance with their terms.
- 10.4 Amendment of Plan. The Administrator may amend, suspend or terminate the Plan at any time; provided that no amendment, other than an increase to the Overall Share Limit, may materially and adversely affect any Award outstanding at the time of such amendment without the affected Participant's consent. No Awards may be granted under the Plan during any suspension period or after Plan termination. Awards outstanding at the time of any Plan suspension or termination will continue to be governed by the Plan and the Award Agreement, as in effect before such suspension or termination. The Board will obtain shareholder approval of any Plan amendment to the extent necessary to comply with Applicable Laws.

10.5 <u>Provisions for Non-US Participants</u>. The Administrator may modify Awards granted to Participants who are non-US nationals or employed outside the United States or establish subplans or procedures under the Plan to address differences in laws, rules, regulations or customs of such jurisdictions outside the United States with respect to tax, securities, currency, employee benefit or other matters.

### 10.6 Section 409A.

- (a) <u>General</u>. The Company intends that all Awards be structured to comply with, or be exempt from, Section 409A, such that no adverse tax consequences, interest, or penalties under Section 409A apply. Notwithstanding anything in the Plan or any Award Agreement to the contrary, the Administrator may, without a Participant's consent, amend this Plan or Awards, adopt policies and procedures, or take any other actions (including amendments, policies, procedures and retroactive actions) as are necessary or appropriate to preserve the intended tax treatment of Awards, including any such actions intended to (A) exempt this Plan or any Award from Section 409A, or (B) comply with Section 409A, including regulations, guidance, compliance programs and other interpretative authority that may be issued after an Award's grant date. The Company makes no representations or warranties as to an Award's tax treatment under Section 409A or otherwise. The Company will have no obligation under this Section 10.6 or otherwise to avoid the taxes, penalties or interest under Section 409A with respect to any Award and will have no liability to any Participant or any other person if any Award, compensation or other benefits under the Plan are determined to constitute noncompliant "nonqualified deferred compensation" subject to taxes, penalties or interest under Section 409A.
- (b) <u>Separation from Service</u>. If an Award constitutes "nonqualified deferred compensation" under Section 409A, any payment or settlement of such Award upon a termination of a Participant's Service Provider relationship will, to the extent necessary to avoid taxes under Section 409A, be made only upon the Participant's "separation from service" (within the meaning of Section 409A), whether such "separation from service" occurs upon or after the termination of the Participant's Service Provider relationship. For purposes of this Plan or any Award Agreement relating to any such payments or benefits, references to a "termination," "termination of employment" or like terms means a "separation from service."
- (c) <u>Payments to Specified Employees</u>. Notwithstanding any contrary provision in the Plan or any Award Agreement, any payment(s) of "nonqualified deferred compensation" required to be made under an Award to a "specified employee" (as defined under Section 409A and as the Administrator determines) due to his or her "separation from service" will, to the extent necessary to avoid taxes under Section 409A(a)(2)(B)(i) of the Code, be delayed for the six-month period immediately following such "separation from service" (or, if earlier, until the specified employee's death) and will instead be paid (as set forth in the Award Agreement) on the day immediately following such six-month period or as soon as administratively practicable thereafter (without interest). Any payments of "nonqualified deferred compensation" under such Award payable more than six months following the Participant's "separation from service" will be paid at the time or times the payments are otherwise scheduled to be made.

10.7 <u>Limitations on Liability</u>. Notwithstanding any other provisions of the Plan, no individual acting as a director, officer, other employee or agent of the Company or any Subsidiary will be liable to any Participant, former Participant, spouse, beneficiary, or any other person for any claim, loss, liability, or expense incurred in connection with the Plan or any Award, and such individual will not be personally liable with respect to the Plan because of any contract or other instrument executed in his or her capacity as an Administrator, director, officer, other employee or agent of the Company or any Subsidiary. The Company will indemnify and hold harmless each director, officer, other employee and agent of the Company or any Subsidiary that has been or will be granted or delegated any duty or power relating to the Plan's administration or interpretation, against any cost or expense (including attorneys' fees) or liability (including any sum paid in settlement of a claim with the Administrator's approval) arising from any act or omission concerning this Plan unless arising from such person's own fraud or bad faith.

10.8 <u>Lock-Up Period</u>. The Company may, at the request of any underwriter representative or otherwise, in connection with registering the offering of any Company securities under the Securities Act, prohibit Participants from, directly or indirectly, selling or otherwise transferring any Shares or other Company securities during a period of up to one hundred eighty days following the effective date of a Company registration statement filed under the Securities Act, or such longer period as determined by the underwriter.

10.9 Data Privacy. As a condition for receiving any Award, each Participant explicitly and unambiguously consents to the collection, use and transfer, in electronic or other form, of personal data as described in this section by and among the Company and its Subsidiaries and affiliates exclusively for implementing, administering and managing the Participant's participation in the Plan. The Company and its Subsidiaries and affiliates may hold certain personal information about a Participant, including the Participant's name, address and telephone number; birthdate; social security, insurance number or other identification number; salary; nationality; job title(s); any Shares held in the Company or its Subsidiaries and affiliates; and Award details, to implement, manage and administer the Plan and Awards (the "Data"). The Company and its Subsidiaries and affiliates may transfer the Data amongst themselves as necessary to implement, administer and manage a Participant's participation in the Plan, and the Company and its Subsidiaries and affiliates may transfer the Data to third parties assisting the Company with Plan implementation, administration and management. These recipients may be located in the Participant's country, or elsewhere, and the Participant's country may have different data privacy laws and protections than the recipients' country. By accepting an Award, each Participant authorizes such recipients to receive, possess, use, retain and transfer the Data, in electronic or other form, to implement, administer and manage the Participant's participation in the Plan, including any required Data transfer to a broker or other third party with whom the Company or the Participant may elect to deposit any Shares. The Data related to a Participant will be held only as long as necessary to implement, administer, and manage the Participant's participation in the Plan. A Participant may, at any time, view the Data that the Company holds regarding such Participant, request additional information about the storage and processing of the Data regarding such Participant, recommend any necessary corrections to the Data regarding the Participant or refuse or withdraw the consents in this Section 10.9 in writing, without cost, by contacting the local human resources representative. The Company may cancel Participant's ability to participate in the Plan and, in the Administrator's discretion, the Participant may forfeit any outstanding Awards if the Participant refuses or withdraws the consents in this Section 10.9. For more information on the consequences of refusing or withdrawing consent, Participants may contact their local human resources representative.

10.10 <u>Severability</u>. If any portion of the Plan or any action taken under it is held illegal or invalid for any reason, the illegality or invalidity will not affect the remaining parts of the Plan, and the Plan will be construed and enforced as if the illegal or invalid provisions had been excluded, and the illegal or invalid action will be null and void.

- 10.11 <u>Governing Documents</u>. If any contradiction occurs between the Plan and any Award Agreement or other written agreement between a Participant and the Company (or any Subsidiary) that the Administrator has approved, the Plan will govern, unless it is expressly specified in such Award Agreement or other written document that a specific provision of the Plan will not apply.
- 10.12 <u>Governing Law</u>. The Plan and all Awards will be governed by and interpreted in accordance with the laws of the Cayman Islands, disregarding any choice-of-law principles requiring the application of a jurisdiction's laws other than the Cayman Islands.
- 10.13 <u>Claw-back Provisions</u>. All Awards (including any proceeds, gains or other economic benefit the Participant actually or constructively receives upon receipt or exercise of any Award or the receipt or resale of any Shares underlying the Award) will be subject to any Company claw-back policy, including any claw-back policy adopted to comply with Applicable Laws (including the Dodd-Frank Wall Street Reform and Consumer Protection Act and any rules or regulations promulgated thereunder) as set forth in such claw-back policy or the Award Agreement.
- 10.14 <u>Titles and Headings</u>. The titles and headings in the Plan are for convenience of reference only and, if any conflict, the Plan's text, rather than such titles or headings, will control.
- 10.15 <u>Conformity to Securities Laws</u>. Participant acknowledges that the Plan is intended to conform to the extent necessary with Applicable Laws. Notwithstanding anything herein to the contrary, the Plan and all Awards will be administered only in conformance with Applicable Laws. To the extent Applicable Laws permit, the Plan and all Award Agreements will be deemed amended as necessary to conform to Applicable Laws.
- 10.16 <u>Relationship to Other Benefits</u>. No payment under the Plan will be taken into account in determining any benefits under any pension, retirement, savings, profit sharing, group insurance, welfare or other benefit plan of the Company or any Subsidiary except as expressly provided in writing in such other plan or an agreement thereunder.
- 10.17 <u>Broker-Assisted Sales</u>. In the event of a broker-assisted sale of Shares in connection with the payment of amounts owed by a Participant under or with respect to the Plan or Awards, including amounts to be paid under the final sentence of Section 9.5: (a) any Shares to be sold through the broker-assisted sale will be sold on the day the payment first becomes due, or as soon thereafter as practicable; (b) such Shares may be sold as part of a block trade with other Participants in the Plan in which all participants receive an average price; (c) the applicable Participant will be responsible for all broker's fees and other costs of sale, and by accepting an Award, each Participant agrees to indemnify and hold the Company harmless from any losses, costs, damages, or expenses relating to any such sale; (d) to the extent the Company or its designee receives proceeds of such sale that exceed the amount owed, the Company will pay such excess in cash to the applicable Participant as soon as reasonably practicable; (e) the Company and its designees are under no obligation to arrange for such sale at any particular price; and (f) in the event the proceeds of such sale are insufficient to satisfy the Participant's applicable obligation, the Participant may be required to pay immediately upon demand to the Company or its designee an amount in cash sufficient to satisfy any remaining portion of the Participant's obligation.

# ARTICLE XI. DEFINITIONS

As used in the Plan, the following words and phrases will have the following meanings:

- 11.1 "*Administrator*" means the Board or a Committee to the extent that the Board's powers or authority under the Plan have been delegated to such Committee.
- 11.2 "*Applicable Laws*" means the requirements relating to the administration of equity incentive plans under Cayman Islands and U.S. federal and state securities, tax and other applicable laws, rules and regulations, the applicable rules of any stock exchange or quotation system on which the Ordinary Shares are listed or quoted and the applicable laws and rules of any other country or jurisdiction where Awards are granted or governed.
- 11.3 "Award" means, individually or collectively, a grant under the Plan of Options, Share Appreciation Rights, Restricted Shares, Restricted Share Units or Other Share or Cash Based Awards.
- 11.4 "*Award Agreement*" means a written agreement evidencing an Award, which may be electronic, that contains such terms and conditions as the Administrator determines, consistent with and subject to the terms and conditions of the Plan.
  - 11.5 "Board" means the Board of Directors of the Company.
- 11.6 "Cause" means (i) if a Participant is a party to a written employment or consulting agreement with the Company or any of its Subsidiaries or an Award Agreement in which the term "cause" is defined (a "Relevant Agreement"), "Cause" as defined in the Relevant Agreement, and (ii) if no Relevant Agreement exists, (A) the Administrator's determination that the Participant failed to substantially perform the Participant's duties (other than a failure resulting from the Participant's Disability); (B) the Administrator's determination that the Participant failed to carry out, or comply with any lawful and reasonable directive of the Board or the Participant's immediate supervisor; (C) the occurrence of any act or omission by the Participant that could reasonably be expected to result in (or has resulted in) the Participant's conviction, plea of no contest, plea of nolo contendere, or imposition of unadjudicated probation for any felony or indictable offense or crime involving moral turpitude; (D) the Participant's unlawful use (including being under the influence) or possession of illegal drugs on the premises of the Company or any of its Subsidiaries or while performing the Participant's duties and responsibilities for the Company or any of its Subsidiaries; or (E) the Participant's commission of an act of fraud, embezzlement, misappropriation, misconduct, or breach of fiduciary duty against the Company or any of its Subsidiaries.
  - 11.7 "Change in Control" means and includes each of the following:
- (a) A transaction or series of transactions (other than an offering of Ordinary Shares to the general public through a registration statement filed with the Securities and Exchange Commission or a transaction or series of transactions that meets the requirements of clauses (i) and (ii) of subsection (c) below) whereby any "person" or related "group" of "persons" (as such terms are used in Sections 13(d) and 14(d)(2) of the Exchange Act) (other than the Company, any of its Subsidiaries, an employee benefit plan maintained by the Company or any of its Subsidiaries or a "person" that, prior to such transaction, directly or indirectly controls, is controlled by, or is under common control with, the Company) directly or indirectly acquires beneficial ownership (within the meaning of Rule 13d-3 under the Exchange Act) of securities of the Company possessing more than 50% of the total combined voting power of the Company's securities outstanding immediately after such acquisition; or
- (b) During any period of two consecutive years, individuals who, at the beginning of such period, constitute the Board together with any new Director(s) (other than a Director designated by a person who shall have entered into an agreement with the Company to effect a transaction described in subsections (a) or (c)) whose election by the Board or nomination for election by the Company's shareholders was approved by a vote of at least two-thirds of the Directors then still in office who either were Directors at the beginning of the two-year period or whose election or nomination for election was previously so approved, cease for any reason to constitute a majority thereof; or

- (c) The consummation by the Company (whether directly involving the Company or indirectly involving the Company through one or more intermediaries) of (x) a merger, consolidation, reorganization, or business combination or (y) a sale or other disposition of all or substantially all of the Company's assets in any single transaction or series of related transactions or (z) the acquisition of assets or stock of another entity, in each case other than a transaction:
- (i) which results in the Company's voting securities outstanding immediately before the transaction continuing to represent (either by remaining outstanding or by being converted into voting securities of the Company or the person that, as a result of the transaction, controls, directly or indirectly, the Company or owns, directly or indirectly, all or substantially all of the Company's assets or otherwise succeeds to the business of the Company (the Company or such person, the "Successor Entity")) directly or indirectly, at least a majority of the combined voting power of the Successor Entity's outstanding voting securities immediately after the transaction, and
- (ii) after which no person or group beneficially owns voting securities representing 50% or more of the combined voting power of the Successor Entity; provided, however, that no person or group shall be treated for purposes of this clause (ii) as beneficially owning 50% or more of the combined voting power of the Successor Entity solely as a result of the voting power held in the Company prior to the consummation of the transaction.

Notwithstanding the foregoing, if a Change in Control constitutes a payment event with respect to any Award (or portion of any Award) that provides for the deferral of compensation that is subject to Section 409A, to the extent required to avoid the imposition of additional taxes under Section 409A, the transaction or event described in subsection (a), (b) or (c) with respect to such Award (or portion thereof) shall only constitute a Change in Control for purposes of the payment timing of such Award if such transaction also constitutes a "change in control event," as defined in Treasury Regulation Section 1.409A-3(i)(5).

The Administrator shall have full and final authority, which shall be exercised in its discretion, to determine conclusively whether a Change in Control has occurred pursuant to the above definition, the date of the occurrence of such Change in Control and any incidental matters relating thereto; provided that any exercise of authority in conjunction with a determination of whether a Change in Control is a "change in control event" as defined in Treasury Regulation Section 1.409A-3(i)(5) shall be consistent with such regulation.

- 11.8 "Code" means the Internal Revenue Code of 1986, as amended, and the regulations issued thereunder.
- 11.9 "Committee" means one or more committees or subcommittees of the Board, which may include one or more Company directors or executive officers, to the extent Applicable Laws permit. To the extent required to comply with the provisions of Rule 16b-3, it is intended that each member of the Committee will be, at the time the Committee takes any action with respect to an Award that is subject to Rule 16b-3, a "non-employee director" within the meaning of Rule 16b-3; however, a Committee member's failure to qualify as a "non-employee director" within the meaning of Rule 16b-3 will not invalidate any Award granted by the Committee that is otherwise validly granted under the Plan.

- 11.10 "Company" means MeiraGTx Holdings plc, an exempted company limited by shares incorporated under the laws of the Cayman Islands, or any successor.
- 11.11 "Consultant" means any person, including any adviser, engaged by the Company or its parent or Subsidiary to render services to such entity if the consultant or adviser: (i) renders bona fide services to the Company; (ii) renders services not in connection with the offer or sale of securities in a capital-raising transaction and does not directly or indirectly promote or maintain a market for the Company's securities; and (iii) is a natural person.
- 11.12 "*Designated Beneficiary*" means the beneficiary or beneficiaries the Participant designates, in a manner the Administrator determines, to receive amounts due or exercise the Participant's rights if the Participant dies or becomes incapacitated. Without a Participant's effective designation, "Designated Beneficiary" will mean the Participant's estate.
  - 11.13 "Director" means a Board member.
  - 11.14 "Disability" means a permanent and total disability under Section 22(e)(3) of the Code, as amended.
- 11.15 "*Dividend Equivalents*" means a right granted to a Participant under the Plan to receive the equivalent value (in cash or Shares) of dividends paid on Shares.
  - 11.16 "Employee" means any employee of the Company or its Subsidiaries.
- 11.17 "Equity Restructuring" means a nonreciprocal transaction between the Company and its shareholders, such as a share dividend, share split, share consolidation, spin-off or recapitalization through a large, nonrecurring cash dividend, that affects the number or kind of Shares (or other Company securities) or the share price of Ordinary Shares (or other Company securities) and causes a change in the per share value of the Ordinary Shares underlying outstanding Awards.
  - 11.18 "Exchange Act" means the Securities Exchange Act of 1934, as amended.
- 11.19 "Fair Market Value" means, as of any date, the value of Ordinary Shares determined as follows: (i) if the Ordinary Shares are listed on any established stock exchange, its Fair Market Value will be the closing sales price for such Ordinary Shares as quoted on such exchange for such date, or if no sale occurred on such date, the last day preceding such date during which a sale occurred, as reported in The Wall Street Journal or another source the Administrator deems reliable; (ii) if the Ordinary Shares are not traded on a stock exchange but is quoted on a national market or other quotation system, the closing sales price on such date, or if no sales occurred on such date, then on the last date preceding such date during which a sale occurred, as reported in The Wall Street Journal or another source the Administrator deems reliable; or (iii) without an established market for the Ordinary Shares, the Administrator will determine the Fair Market Value in its discretion. Notwithstanding the foregoing, with respect to any Award granted on the pricing date of the Company's initial public offering, the Fair Market Value shall mean the initial public offering price of a Share as set forth in the Company's final prospectus relating to its initial public offering filed with the Securities and Exchange Commission.
- 11.20 "*Greater Than 10% Shareholder*" means an individual then owning (within the meaning of Section 424(d) of the Code) more than 10% of the total combined voting power of all classes of shares of the Company or its parent or subsidiary corporation, as defined in Section 424(e) and (f) of the Code, respectively.

- 11.21 "Incentive Stock Option" means an Option intended to qualify as an "incentive stock option" as defined in Section 422 of the Code.
- 11.22 "Non-Qualified Stock Option" means an Option not intended or not qualifying as an Incentive Stock Option.
- 11.23 "Option" means an option to purchase Shares.
- 11.24 "Ordinary Shares" means the ordinary shares of the Company.
- 11.25 "Other Share or Cash Based Awards" means cash awards, awards of Shares, and other awards valued wholly or partially by referring to, or are otherwise based on, Shares or other property.
- 11.26 "Overall Share Limit" means the sum of (i) 3,054,996 Shares; (ii) any Ordinary Shares which are subject to Prior Plan Awards which become available for issuance under the Plan pursuant to Article IV and (iii) an annual increase on the first day of each calendar year beginning January 1, 2019 and ending on and including January 1, 2028, equal to the lesser of (A) 4% of the aggregate number of Shares outstanding on the final day of the immediately preceding calendar year and (B) such smaller number of Shares as is determined by the Board.
  - 11.27 "Participant" means a Service Provider who has been granted an Award.
- 11.28 "Performance Criteria" mean the criteria (and adjustments) that the Administrator may select for an Award to establish performance goals for a performance period, which may include the following: net earnings or losses (either before or after one or more of interest, taxes, depreciation, amortization, and non-cash equity-based compensation expense); gross or net sales or revenue or sales or revenue growth; net income (either before or after taxes) or adjusted net income; profits (including but not limited to gross profits, net profits, profit growth, net operation profit or economic profit), profit return ratios or operating margin; budget or operating earnings (either before or after taxes or before or after allocation of corporate overhead and bonus); cash flow (including operating cash flow and free cash flow or cash flow return on capital); return on assets; return on capital or invested capital; cost of capital; return on shareholders' equity; total shareholder return; return on sales; costs, reductions in costs and cost control measures; expenses; working capital; earnings or loss per share; adjusted earnings or loss per share; price per share or dividends per share (or appreciation in or maintenance of such price or dividends); regulatory achievements or compliance; implementation, completion or attainment of objectives relating to research, development, regulatory, commercial, or strategic milestones or developments; market share; economic value or economic value added models; division, group or corporate financial goals; customer satisfaction/growth; customer service; employee satisfaction; recruitment and maintenance of personnel; human resources management; supervision of litigation and other legal matters; strategic partnerships and transactions; financial ratios (including those measuring liquidity, activity, profitability or leverage); debt levels or reductions; sales-related goals; financing and other capital raising transactions; cash on hand; acquisition activity; investment sourcing activity; and marketing initiatives, any of which may be measured in absolute terms or as compared to any incremental increase or decrease. Such performance goals also may be based solely by reference to the Company's performance or the performance of a Subsidiary, division, business segment or business unit of the Company or a Subsidiary, or based upon performance relative to performance of other companies or upon comparisons of any of the indicators of performance relative to performance of other companies. The Committee may provide for exclusion of the impact of an event or occurrence which the Committee determines should appropriately be excluded, including (a) restructurings, discontinued operations, extraordinary items, and other unusual, infrequently occurring or non-recurring charges or events, (b) asset write-downs, (c) litigation or claim judgments or settlements, (d) acquisitions or divestitures, (e)

reorganization or change in the corporate structure or capital structure of the Company, (f) an event either not directly related to the operations of the Company, Subsidiary, division, business segment or business unit or not within the reasonable control of management, (g) foreign exchange gains and losses, (h) a change in the fiscal year of the Company, (i) the refinancing or repurchase of bank loans or debt securities, (j) unbudgeted capital expenditures, (k) the issuance or repurchase of equity securities and other changes in the number of outstanding shares, (l) conversion of some or all of convertible securities to Ordinary Shares, (m) any business interruption event (n) the cumulative effects of tax or accounting changes in accordance with U.S. generally accepted accounting principles, or (o) the effect of changes in other laws or regulatory rules affecting reported results.

- 11.29 "Plan" means this 2018 Incentive Award Plan.
- 11.30 "*Prior Plans*" means, collectively, the MeiraGTx Limited 2016 Equity Incentive Plan and any prior equity incentive plans of the Company or its predecessor.
  - 11.31 "Prior Plan Award" means an award outstanding under the Prior Plans as of the Plan's effective date in Section 10.3.
- 11.32 "*Public Trading Date*" means the first date upon which the Ordinary Shares are listed (or approved for listing) upon notice of issuance on any securities exchange or designated (or approved for designation) upon notice of issuance as a national market security on an interdealer quotation system, or, if earlier, the date on which the Company becomes a "publicly held corporation" for purposes of Treasury Regulation Section 1.162-27(c)(1).
  - 11.33 "Restricted Shares" means Shares awarded to a Participant under Article VI subject to certain vesting conditions and other restrictions.
- 11.34 "Restricted Share Unit" means an unfunded, unsecured right to receive, on the applicable settlement date, one Share or an amount in cash or other consideration determined by the Administrator to be of equal value as of such settlement date, subject to certain vesting conditions and other restrictions.
  - 11.35 "Rule 16b-3" means Rule 16b-3 promulgated under the Exchange Act.
- 11.36 "Section 409A" means Section 409A of the Code and all regulations, guidance, compliance programs and other interpretative authority thereunder.
  - 11.37 "Securities Act" means the Securities Act of 1933, as amended.
  - 11.38 "Service Provider" means an Employee, Consultant or Director.
  - 11.39 "Share" or "Shares" means an Ordinary Share or Ordinary Shares.
  - 11.40 "Share Appreciation Right" means a share appreciation right granted under Article V.
- 11.41 "*Subsidiary*" means any entity (other than the Company), whether domestic or foreign, in an unbroken chain of entities beginning with the Company if each of the entities other than the last entity in the unbroken chain beneficially owns, at the time of the determination, securities or interests representing at least 50% of the total combined voting power of all classes of securities or interests in one of the other entities in such chain.

11.42 "*Substitute Awards*" shall mean Awards granted or Shares issued by the Company in assumption of, or in substitution or exchange for, awards previously granted, or the right or obligation to make future awards, in each case by a company acquired by the Company or any Subsidiary or with which the Company or any Subsidiary combines.

11.43 "*Termination of Service*" means the date the Participant ceases to be a Service Provider.

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### MEIRAGTX HOLDINGS PLC 2018 INCENTIVE AWARD PLAN

### **OPTION GRANT NOTICE**

Capitalized terms not specifically defined in this Option Grant Notice (the "*Grant Notice*") have the meanings given to them in the 2018 Incentive Award Plan (as amended from time to time, the "*Plan*") of MeiraGTx Holdings plc (the "*Company*").

The Company has granted to the participant listed below ("*Participant*") the option described in this Grant Notice (the "*Option*"), subject to the terms and conditions of the Plan and the Option Agreement attached as **Exhibit A** (the "*Agreement*"), both of which are incorporated into this Grant Notice by reference.

Participant:	
Grant Date:	
Exercise Price per Share:	
Shares Subject to the Option:	
Final Expiration Date:	
Vesting Commencement Date:	
Vesting Schedule:	[To be specified in individual award agreements]
Type of Option	[Incentive Stock Option/Non-Qualified Stock Option]
reviewed the Plan, this Grant Notice and the Agreement in their entirety, ha	the terms of this Grant Notice, the Plan and the Agreement. Participant has as had an opportunity to obtain the advice of counsel prior to executing this Grant and the Agreement. Participant hereby agrees to accept as binding, conclusive and as arising under the Plan, this Grant Notice or the Agreement.
MEIRAGTX HOLDINGS PLC	PARTICIPANT
By:	
Name:	[Participant Name]
Tide.	

#### **OPTION AGREEMENT**

Capitalized terms not specifically defined in this Agreement have the meanings specified in the Grant Notice or, if not defined in the Grant Notice, in the Plan.

### ARTICLE I. GENERAL

- 1.1 Grant of Option. The Company has granted to Participant the Option effective as of the grant date set forth in the Grant Notice (the "Grant Date").
- 1.2 <u>Incorporation of Terms of Plan</u>. The Option is subject to the terms and conditions set forth in this Agreement and the Plan, which is incorporated herein by reference. In the event of any inconsistency between the Plan and this Agreement, the terms of the Plan will control.

# ARTICLE II. PERIOD OF EXERCISABILITY

- 2.1 <u>Commencement of Exercisability.</u> The Option will vest and become exercisable according to the vesting schedule in the Grant Notice (the "*Vesting Schedule*") except that any fraction of a Share as to which the Option would be vested or exercisable will be accumulated and will vest and become exercisable only when a whole Share has accumulated. Notwithstanding anything in the Grant Notice, the Plan or this Agreement to the contrary, unless the Administrator otherwise determines, the Option will immediately expire and be forfeited as to any portion that is not vested and exercisable as of Participant's Termination of Service for any reason.
- 2.2 <u>Duration of Exercisability</u>. The Vesting Schedule is cumulative. Any portion of the Option which vests and becomes exercisable will remain vested and exercisable until the Option expires. The Option will be forfeited immediately upon its expiration.
  - 2.3 Expiration of Option. The Option may not be exercised to any extent by anyone after, and will expire on, the first of the following to occur:
    - (a) The final expiration date in the Grant Notice;
- (b) Except as the Administrator may otherwise approve, the expiration of three (3) months from the date of Participant's Termination of Service, unless Participant's Termination of Service is for Cause or by reason of Participant's death or Disability;
- (c) Except as the Administrator may otherwise approve, the expiration of one (1) year from the date of Participant's Termination of Service by reason of Participant's death or Disability; and
  - (d) Except as the Administrator may otherwise approve, Participant's Termination of Service for Cause.

### ARTICLE III. EXERCISE OF OPTION

- 3.1 <u>Person Eligible to Exercise</u>. During Participant's lifetime, only Participant may exercise the Option. After Participant's death, any exercisable portion of the Option may, prior to the time the Option expires, be exercised by Participant's Designated Beneficiary as provided in the Plan.
- 3.2 <u>Partial Exercise</u>. Any exercisable portion of the Option or the entire Option, if then wholly exercisable, may be exercised, in whole or in part, according to the procedures in the Plan at any time prior to the time the Option or portion thereof expires, except that the Option may only be exercised for whole Shares.

### 3.3 Tax Withholding.

- (a) The Company has the right and option, but not the obligation, to treat Participant's failure to provide timely payment in accordance with the Plan of any withholding tax arising in connection with the Option as Participant's election to satisfy all or any portion of the withholding tax by requesting the Company retain Shares otherwise issuable under the Option.
- (b) Participant acknowledges that Participant is ultimately liable and responsible for all taxes owed in connection with the Option, regardless of any action the Company or any Subsidiary takes with respect to any tax withholding obligations that arise in connection with the Option. Neither the Company nor any Subsidiary makes any representation or undertaking regarding the treatment of any tax withholding in connection with the awarding, vesting or exercise of the Option or the subsequent sale of Shares. The Company and the Subsidiaries do not commit and are under no obligation to structure the Option to reduce or eliminate Participant's tax liability.

# ARTICLE IV. OTHER PROVISIONS

- 4.1 <u>Adjustments</u>. Participant acknowledges that the Option is subject to adjustment, modification and termination in certain events as provided in this Agreement and the Plan.
- 4.2 Notices. Any notice to be given under the terms of this Agreement to the Company must be in writing and addressed to the Company in care of the Company's Secretary at the Company's principal office or the Secretary's then-current email address or facsimile number. Any notice to be given under the terms of this Agreement to Participant must be in writing and addressed to Participant (or, if Participant is then deceased, to the person entitled to exercise the Option) at Participant's last known mailing address, email address or facsimile number in the Company's personnel files. By a notice given pursuant to this Section, either party may designate a different address for notices to be given to that party. Any notice will be deemed duly given when actually received, when sent by email, when sent by certified mail (return receipt requested) and deposited with postage prepaid in a post office or branch post office regularly maintained by the United States Postal Service, when delivered by a nationally recognized express shipping company or upon receipt of a facsimile transmission confirmation.
  - 4.3 Titles. Titles are provided herein for convenience only and are not to serve as a basis for interpretation or construction of this Agreement.
- 4.4 <u>Conformity to Securities Laws</u>. Participant acknowledges that the Plan, the Grant Notice and this Agreement are intended to conform to the extent necessary with all Applicable Laws and, to the extent Applicable Laws permit, will be deemed amended as necessary to conform to Applicable Laws.

- 4.5 <u>Successors and Assigns</u>. The Company may assign any of its rights under this Agreement to single or multiple assignees, and this Agreement will inure to the benefit of the successors and assigns of the Company. Subject to the restrictions on transfer set forth in the Plan, this Agreement will be binding upon and inure to the benefit of the heirs, legatees, legal representatives, successors and assigns of the parties hereto.
- 4.6 <u>Limitations Applicable to Section 16 Persons</u>. Notwithstanding any other provision of the Plan or this Agreement, if Participant is subject to Section 16 of the Exchange Act, the Plan, the Grant Notice, this Agreement and the Option will be subject to any additional limitations set forth in any applicable exemptive rule under Section 16 of the Exchange Act (including any amendment to Rule 16b-3) that are requirements for the application of such exemptive rule. To the extent Applicable Laws permit, this Agreement will be deemed amended as necessary to conform to such applicable exemptive rule.
- 4.7 Entire Agreement . The Plan, the Grant Notice and this Agreement (including any exhibit hereto) constitute the entire agreement of the parties and supersede in their entirety all prior undertakings and agreements of the Company and Participant with respect to the subject matter hereof.
- 4.8 <u>Agreement Severable</u>. In the event that any provision of the Grant Notice or this Agreement is held illegal or invalid, the provision will be severable from, and the illegality or invalidity of the provision will not be construed to have any effect on, the remaining provisions of the Grant Notice or this Agreement.
- 4.9 <u>Limitation on Participant's Rights</u>. Participation in the Plan confers no rights or interests other than as herein provided. This Agreement creates only a contractual obligation on the part of the Company as to amounts payable and may not be construed as creating a trust. Neither the Plan nor any underlying program, in and of itself, has any assets. Participant will have only the rights of a general unsecured creditor of the Company with respect to amounts credited and benefits payable, if any, with respect to the Option, and rights no greater than the right to receive the Shares as a general unsecured creditor with respect to the Option, as and when exercised pursuant to the terms hereof.
- 4.10 Not a Contract of Employment. Nothing in the Plan, the Grant Notice or this Agreement confers upon Participant any right to continue in the employ or service of the Company or any Subsidiary or interferes with or restricts in any way the rights of the Company and its Subsidiaries, which rights are hereby expressly reserved, to discharge or terminate the services of Participant at any time for any reason whatsoever, with or without Cause, except to the extent expressly provided otherwise in a written agreement between the Company or a Subsidiary and Participant.
- 4.11 <u>Counterparts</u>. The Grant Notice may be executed in one or more counterparts, including by way of any electronic signature, subject to Applicable Law, each of which will be deemed an original and all of which together will constitute one instrument.
  - 4.12 <u>Incentive Stock Options</u>. If the Option is designated as an Incentive Stock Option:
- (a) Participant acknowledges that to the extent the aggregate fair market value of shares (determined as of the time the option with respect to the shares is granted) with respect to which options intended to qualify as "incentive stock options" under Section 422 of the Code, including the Option, are exercisable for the first time by Participant during any calendar year exceeds \$100,000 or if for any other reason such options do not qualify or cease to qualify for treatment as "incentive stock options" under Section 422 of the Code, such options (including the Option) will be treated as non-qualified stock options. Participant further acknowledges that the rule set forth in the preceding sentence

will be applied by taking the Option and other options into account in the order in which they were granted, as determined under Section 422(d) of the Code. Participant acknowledges that amendments or modifications made to the Option pursuant to the Plan that would cause the Option to become a Non-Qualified Stock Option will not materially or adversely affect Participant's rights under the Option, and that any such amendment or modification shall not require Participant's consent. Participant also acknowledges that if the Option is exercised more than three (3) months after Participant's Termination of Service as an Employee, other than by reason of death or disability, the Option will be taxed as a Non-Qualified Stock Option.

(b) Participant will give prompt written notice to the Company of any disposition or other transfer of any Shares acquired under this Agreement if such disposition or other transfer is made (a) within two (2) years from the Grant Date or (b) within one (1) year after the transfer of such Shares to Participant. Such notice will specify the date of such disposition or other transfer and the amount realized, in cash, other property, assumption of indebtedness or other consideration, by Participant in such disposition or other transfer.

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# MEIRAGTX HOLDINGS PLC 2018 INCENTIVE AWARD PLAN

# RESTRICTED SHARE UNIT GRANT NOTICE

Capitalized terms not specifically defined in this Restricted Share Unit Grant Notice (the "*Grant Notice*") have the meanings given to them in the 2018 Incentive Award Plan (as amended from time to time, the "*Plan*") of MeiraGTx Holdings plc (the "*Company*").

The Company has granted to the participant listed below ("*Participant*") the Restricted Share Units described in this Grant Notice (the "*RSUs*"), subject to the terms and conditions of the Plan and the Restricted Share Unit Agreement attached as **Exhibit A** (the "*Agreement*"), both of which are incorporated into this Grant Notice by reference.

Participant:

Grant Date:	
Number of RSUs:	
<b>Vesting Commencement Date:</b>	
Vesting Schedule:	[To be specified in individual award agreements]
reviewed the Plan, this Grant Notice and the Agreem Notice and fully understands all provisions of the Pla	grees to be bound by the terms of this Grant Notice, the Plan and the Agreement. Participant has ent in their entirety, has had an opportunity to obtain the advice of counsel prior to executing this Grant an, this Grant Notice and the Agreement. Participant hereby agrees to accept as binding, conclusive and ator upon any questions arising under the Plan, this Grant Notice or the Agreement.
MEIRAGTX HOLDINGS PLC	PARTICIPANT
By:	
Name:	[Participant Name]
Trial	

#### RESTRICTED SHARE UNIT AGREEMENT

Capitalized terms not specifically defined in this Agreement have the meanings specified in the Grant Notice or, if not defined in the Grant Notice, in the Plan.

## ARTICLE I. GENERAL

## 1.1 Award of RSUs and Dividend Equivalents.

- (a) The Company has granted the RSUs to Participant effective as of the grant date set forth in the Grant Notice (the "*Grant Date*"). Each RSU represents the right to receive one Share or, at the option of the Company, an amount of cash, in either case, as set forth in this Agreement. Participant will have no right to the distribution of any Shares or payment of any cash until the time (if ever) the RSUs have vested.
- (b) The Company hereby grants to Participant, with respect to each RSU, a Dividend Equivalent for ordinary cash dividends paid to substantially all holders of outstanding Shares with a record date after the Grant Date and prior to the date the applicable RSU is settled, forfeited or otherwise expires. Each Dividend Equivalent entitles Participant to receive the equivalent value of any such ordinary cash dividends paid on a single Share. The Company will establish a separate Dividend Equivalent bookkeeping account (a "Dividend Equivalent Account") for each Dividend Equivalent and credit the Dividend Equivalent Account (without interest) on the applicable dividend payment date with the amount of any such cash paid.
- 1.2 <u>Incorporation of Terms of Plan</u>. The RSUs are subject to the terms and conditions set forth in this Agreement and the Plan, which is incorporated herein by reference. In the event of any inconsistency between the Plan and this Agreement, the terms of the Plan will control.
- 1.3 <u>Unsecured Promise</u>. The RSUs and Dividend Equivalents will at all times prior to settlement represent an unsecured Company obligation payable only from the Company's general assets.

# ARTICLE II. VESTING; FORFEITURE AND SETTLEMENT

2.1 <u>Vesting; Forfeiture</u>. The RSUs will vest according to the vesting schedule in the Grant Notice except that any fraction of an RSU that would otherwise be vested will be accumulated and will vest only when a whole RSU has accumulated. In the event of Participant's Termination of Service for any reason, all unvested RSUs will immediately and automatically be cancelled and forfeited, except as otherwise determined by the Administrator or provided in a binding written agreement between Participant and the Company. Dividend Equivalents (including any Dividend Equivalent Account balance) will vest or be forfeited, as applicable, upon the vesting or forfeiture of the RSU with respect to which the Dividend Equivalent (including the Dividend Equivalent Account) relates.

# 2.2 Settlement.

(a) RSUs and Dividend Equivalents (including any Dividend Equivalent Account balance) will be paid in Shares or cash at the Company's option as soon as administratively practicable after the vesting of the applicable RSU, but in no event more than sixty (60) days after the RSU's vesting date. Notwithstanding the foregoing, the Company may delay any payment under this Agreement that the Company reasonably determines would violate Applicable Law until the earliest date the Company reasonably determines the making of the payment will not cause such a violation (in accordance with Treasury Regulation Section 1.409A-2(b)(7)(ii)), provided the Company reasonably believes the delay will not result in the imposition of excise taxes under Section 409A.

(b) If an RSU is paid in cash, the amount of cash paid with respect to the RSU will equal the Fair Market Value of a Share on the day immediately preceding the payment date. If a Dividend Equivalent is paid in Shares, the number of Shares paid with respect to the Dividend Equivalent will equal the quotient, rounded down to the nearest whole Share, of the Dividend Equivalent Account balance divided by the Fair Market Value of a Share on the day immediately preceding the payment date.

# ARTICLE III. TAXATION AND TAX WITHHOLDING

3.1 <u>Representation</u>. Participant represents to the Company that Participant has reviewed with Participant's own tax advisors the tax consequences of this Award and the transactions contemplated by the Grant Notice and this Agreement. Participant is relying solely on such advisors and not on any statements or representations of the Company or any of its agents.

# 3.2 Tax Withholding.

- (a) The Company has the right and option, but not the obligation, to treat Participant's failure to provide timely payment in accordance with the Plan of any withholding tax arising in connection with the RSUs or Dividend Equivalents as Participant's election to satisfy all or any portion of the withholding tax by requesting the Company retain Shares otherwise issuable under the Award.
- (b) Participant acknowledges that Participant is ultimately liable and responsible for all taxes owed in connection with the RSUs and the Dividend Equivalents, regardless of any action the Company or any Subsidiary takes with respect to any tax withholding obligations that arise in connection with the RSUs or Dividend Equivalents. Neither the Company nor any Subsidiary makes any representation or undertaking regarding the treatment of any tax withholding in connection with the awarding, vesting or payment of the RSUs or the Dividend Equivalents or the subsequent sale of Shares. The Company and the Subsidiaries do not commit and are under no obligation to structure the RSUs or Dividend Equivalents to reduce or eliminate Participant's tax liability.

# ARTICLE IV. OTHER PROVISIONS

- 4.1 <u>Adjustments</u>. Participant acknowledges that the RSUs, the Shares subject to the RSUs and the Dividend Equivalents are subject to adjustment, modification and termination in certain events as provided in this Agreement and the Plan.
- 4.2 <u>Notices</u>. Any notice to be given under the terms of this Agreement to the Company must be in writing and addressed to the Company in care of the Company's Secretary at the Company's principal office or the Secretary's then-current email address or facsimile number. Any notice to be given under the terms of this Agreement to Participant must be in writing and addressed to Participant at Participant's last known mailing address, email address or facsimile number in the Company's personnel files. By a notice given pursuant to this Section, either party may designate a different address for notices to be given to that party. Any notice will be deemed duly given when actually received, when sent by email, when sent by certified mail (return receipt requested) and deposited with postage prepaid in a post office or branch post office regularly maintained by the United States Postal Service, when delivered by a nationally recognized express shipping company or upon receipt of a facsimile transmission confirmation.

- 4.3 Titles. Titles are provided herein for convenience only and are not to serve as a basis for interpretation or construction of this Agreement.
- 4.4 <u>Conformity to Securities Laws</u>. Participant acknowledges that the Plan, the Grant Notice and this Agreement are intended to conform to the extent necessary with all Applicable Laws and, to the extent Applicable Laws permit, will be deemed amended as necessary to conform to Applicable Laws.
- 4.5 <u>Successors and Assigns</u>. The Company may assign any of its rights under this Agreement to single or multiple assignees, and this Agreement will inure to the benefit of the successors and assigns of the Company. Subject to the restrictions on transfer set forth in the Plan, this Agreement will be binding upon and inure to the benefit of the heirs, legatees, legal representatives, successors and assigns of the parties hereto.
- 4.6 <u>Limitations Applicable to Section 16 Persons</u>. Notwithstanding any other provision of the Plan or this Agreement, if Participant is subject to Section 16 of the Exchange Act, the Plan, the Grant Notice, this Agreement, the RSUs and the Dividend Equivalents will be subject to any additional limitations set forth in any applicable exemptive rule under Section 16 of the Exchange Act (including any amendment to Rule 16b-3) that are requirements for the application of such exemptive rule. To the extent Applicable Laws permit, this Agreement will be deemed amended as necessary to conform to such applicable exemptive rule.
- 4.7 Entire Agreement. The Plan, the Grant Notice and this Agreement (including any exhibit hereto) constitute the entire agreement of the parties and supersede in their entirety all prior undertakings and agreements of the Company and Participant with respect to the subject matter hereof.
- 4.8 <u>Agreement Severable</u>. In the event that any provision of the Grant Notice or this Agreement is held illegal or invalid, the provision will be severable from, and the illegality or invalidity of the provision will not be construed to have any effect on, the remaining provisions of the Grant Notice or this Agreement.
- 4.9 <u>Limitation on Participant's Rights</u>. Participation in the Plan confers no rights or interests other than as herein provided. This Agreement creates only a contractual obligation on the part of the Company as to amounts payable and may not be construed as creating a trust. Neither the Plan nor any underlying program, in and of itself, has any assets. Participant will have only the rights of a general unsecured creditor of the Company with respect to amounts credited and benefits payable, if any, with respect to the RSUs and Dividend Equivalents, and rights no greater than the right to receive cash or the Shares as a general unsecured creditor with respect to the RSUs and Dividend Equivalents, as and when settled pursuant to the terms of this Agreement.
- 4.10 <u>Not a Contract of Employment</u>. Nothing in the Plan, the Grant Notice or this Agreement confers upon Participant any right to continue in the employ or service of the Company or any Subsidiary or interferes with or restricts in any way the rights of the Company and its Subsidiaries, which rights are hereby expressly reserved, to discharge or terminate the services of Participant at any time for any reason whatsoever, with or without Cause, except to the extent expressly provided otherwise in a written agreement between the Company or a Subsidiary and Participant.
- 4.11 <u>Counterparts</u>. The Grant Notice may be executed in one or more counterparts, including by way of any electronic signature, subject to Applicable Law, each of which will be deemed an original and all of which together will constitute one instrument.

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# MEIRAGTX HOLDINGS PLC 2018 INCENTIVE AWARD PLAN

# RESTRICTED SHARE GRANT NOTICE

Capitalized terms not specifically defined in this Restricted Share Grant Notice (the "*Grant Notice*") have the meanings given to them in the 2018 Incentive Award Plan (as amended from time to time, the "*Plan*") of MeiraGTx Holdings plc (the "*Company*").

Participant: Grant Date:

The Company has granted to the participant listed below ("*Participant*") the Restricted Shares described in this Grant Notice (the "*Restricted Shares*"), subject to the terms and conditions of the Plan and the Restricted Share Agreement attached as **Exhibit A** (the "*Agreement*"), both of which are incorporated into this Grant Notice by reference.

Number of Restricted Snares:		
<b>Vesting Commencement Date:</b>		
Vesting Schedule:	[To be specified in individual award agreements]	
By Participant's signature below, Participant agrees to be bound by the terms of this Grant Notice, the Plan and the Agreement. Participant has reviewed the Plan, this Grant Notice and the Agreement in their entirety, has had an opportunity to obtain the advice of counsel prior to executing this Grant Notice and fully understands all provisions of the Plan, this Grant Notice and the Agreement. Participant hereby agrees to accept as binding, conclusive and final all decisions or interpretations of the Administrator upon any questions arising under the Plan, this Grant Notice or the Agreement.		
MEIRAGTX HOLDINGS PLC	PARTICIPANT	
By:		
Name:	[Participant Name]	
Title:		

#### RESTRICTED SHARE AGREEMENT

Capitalized terms not specifically defined in this Agreement have the meanings specified in the Grant Notice or, if not defined in the Grant Notice, in the Plan.

# ARTICLE I. GENERAL

- 1.1 <u>Issuance of Restricted Shares</u>. The Company will issue the Restricted Shares to the Participant which, for the purposes of this Agreement, shall be treated as issued on the grant date set forth in the Grant Notice and will cause (a) a share certificate or certificates representing the Restricted Shares to be registered in Participant's name if the Company determines to do so or (b) the Restricted Shares to be held in book-entry form. If a share certificate is issued, the certificate will be delivered to, and held in accordance with this Agreement by, the Company or its authorized representatives and will bear the restrictive legends required by this Agreement. If the Restricted Shares are held in book-entry form, then the book-entry will indicate that the Restricted Shares are subject to the restrictions of this Agreement.
- 1.2 <u>Incorporation of Terms of Plan</u>. The Restricted Shares are subject to the terms and conditions set forth in this Agreement and the Plan, which is incorporated herein by reference. In the event of any inconsistency between the Plan and this Agreement, the terms of the Plan will control.

# ARTICLE II. VESTING, FORFEITURE AND ESCROW

- 2.1 <u>Vesting</u>. The Restricted Shares will become vested Shares (the "*Vested Shares*") according to the vesting schedule in the Grant Notice except that any fraction of a Share that would otherwise become a Vested Share will be accumulated and will become a Vested Share only when a whole Vested Share has accumulated.
- 2.2 <u>Forfeiture</u>. In the event of Participant's Termination of Service for any reason, Participant will immediately and automatically forfeit to the Company any Shares that are not Vested Shares (the "*Unvested Shares*") at the time of Participant's Termination of Service, except as otherwise determined by the Administrator or provided in a binding written agreement between Participant and the Company. Upon forfeiture of Unvested Shares, the Company may redeem or repurchase the Unvested Shares for nil consideration and the Participant will have no further rights with respect to the Unvested Shares.

# 2.3 Escrow.

(a) Unvested Shares will be held in escrow by the Company or its authorized representatives until (i) they are forfeited, (ii) they become Vested Shares or (iii) this Agreement is no longer in effect. By accepting this Award, Participant appoints the Company and its authorized representatives as Participant's attorney(s)-in-fact to take all actions necessary to effect any transfer, redemption or surrender of forfeited Unvested Shares (and Retained Distributions (as defined below), if any, paid on such forfeited Unvested Shares) to the Company as may be required pursuant to the Plan or this Agreement and to execute such representations or other documents or assurances as the Company or such representatives deem necessary or advisable in connection with any such transfer. The Company, or its authorized representative, will not be liable for any good faith act or omission with respect to the holding in escrow or transfer of the Restricted Shares.

- (b) All cash dividends and other distributions made or declared with respect to Unvested Shares ("**Retained Distributions**") will be held in escrow by the Company until the time (if ever) when the Unvested Shares to which such Retained Distributions relate become Vested Shares. The Company will establish a separate Retained Distribution bookkeeping account ("**Retained Distribution Account**") for each Unvested Share with respect to which Retained Distributions have been made or declared in cash and credit the Retained Distribution Account (without interest) on the date of payment with the amount of such cash made or declared with respect to the Unvested Share. Retained Distributions (including any Retained Distribution Account balance) will immediately and automatically be forfeited upon forfeiture of the Unvested Share with respect to which the Retained Distributions were paid or declared.
- (c) As soon as reasonably practicable following the date on which an Unvested Share becomes a Vested Share, the Company will (i) if a certificate has been issued, cause the certificate (or a new certificate without the legend required by this Agreement, if Participant so requests) representing the Share to be delivered to Participant or, if the Share is held in book-entry form, cause the notations indicating the Share is subject to the restrictions of this Agreement to be removed and (ii) pay to Participant the Retained Distributions relating to the Share.
- 2.4 <u>Rights as Shareholder</u>. Except as otherwise provided in this Agreement or the Plan, upon issuance of the Restricted Shares by the Company, Participant will have all the rights of a shareholder with respect to the Restricted Shares, including the right to vote the Restricted Shares and to receive dividends or other distributions paid or made with respect to the Restricted Shares.

# ARTICLE III. TAXATION AND TAX WITHHOLDING

- 3.1 <u>Representation</u>. Participant represents to the Company that Participant has reviewed with Participant's own tax advisors the tax consequences of the Restricted Shares and the transactions contemplated by the Grant Notice and this Agreement. Participant is relying solely on such advisors and not on any statements or representations of the Company or any of its agents.
- 3.2 <u>Section 83(b) Election</u>. If Participant makes an election under Section 83(b) of the Code with respect to the Restricted Shares, Participant will deliver a copy of the election to the Company promptly after filing the election with the Internal Revenue Service.

# 3.3 Tax Withholding.

- (a) The Company has the right and option, but not the obligation, to treat Participant's failure to provide timely payment in accordance with the Plan of any withholding tax arising in connection with the Restricted Shares as Participant's election to satisfy all or any portion of the withholding tax by requesting the Company retain Shares otherwise deliverable under the Award.
- (b) Participant acknowledges that Participant is ultimately liable and responsible for all taxes owed in connection with the Restricted Shares, regardless of any action the Company or any Subsidiary takes with respect to any tax withholding obligations that arise in connection with the Restricted Shares. Neither the Company nor any Subsidiary makes any representation or undertaking regarding the treatment of any tax withholding in connection with the awarding, vesting or payment of the Restricted Shares or the subsequent sale of the Restricted Shares. The Company and the Subsidiaries do not commit and are under no obligation to structure this Award to reduce or eliminate Participant's tax liability.

# ARTICLE IV. RESTRICTIVE LEGENDS AND TRANSFERABILITY

- 4.1 <u>Legends</u>. Any certificate representing a Restricted Share will bear the following legend until the Restricted Share becomes a Vested Share:
  - THE SHARES REPRESENTED BY THIS CERTIFICATE ARE SUBJECT TO FORFEITURE IN FAVOR OF THE COMPANY AND MAY BE TRANSFERRED ONLY IN ACCORDANCE WITH THE TERMS OF A RESTRICTED SHARE AGREEMENT BETWEEN THE COMPANY AND THE SHAREHOLDER, A COPY OF WHICH IS ON FILE WITH THE SECRETARY OF THE COMPANY.
- 4.2 <u>Transferability</u>. The Restricted Shares and any Retained Distributions are subject to the restrictions on transfer in the Plan and may not be sold, assigned or transferred in any manner unless and until they become Vested Shares. Any attempted transfer or disposition of Unvested Shares or related Retained Distributions prior to the time the Unvested Shares become Vested Shares will be null and void. The Company will not be required to (a) transfer on its books any Restricted Share that has been sold or otherwise transferred in violation of this Agreement or (b) treat as owner of such Restricted Share or accord the right to vote or pay dividends to any purchaser or other transferee to whom such Restricted Share has been so transferred. The Company may issue appropriate "stop transfer" instructions to its transfer agent, if any, or make appropriate notations to the same effect in its records.

# ARTICLE V. OTHER PROVISIONS

- 5.1 <u>Adjustments</u>. Participant acknowledges that the Restricted Shares are subject to adjustment, modification and termination in certain events as provided in this Agreement and the Plan.
- 5.2 Notices. Any notice to be given under the terms of this Agreement to the Company must be in writing and addressed to the Company in care of the Company's Secretary at the Company's principal office or the Secretary's then-current email address or facsimile number. Any notice to be given under the terms of this Agreement to Participant must be in writing and addressed to Participant at Participant's last known mailing address, email address or facsimile number in the Company's personnel files. By a notice given pursuant to this Section, either party may designate a different address for notices to be given to that party. Any notice will be deemed duly given when actually received, when sent by email, when sent by certified mail (return receipt requested) and deposited with postage prepaid in a post office or branch post office regularly maintained by the United States Postal Service, when delivered by a nationally recognized express shipping company or upon receipt of a facsimile transmission confirmation.
  - 5.3 <u>Titles</u>. Titles are provided herein for convenience only and are not to serve as a basis for interpretation or construction of this Agreement.
- 5.4 <u>Conformity to Securities Laws</u>. Participant acknowledges that the Plan, the Grant Notice and this Agreement are intended to conform to the extent necessary with all Applicable Laws and, to the extent Applicable Laws permit, will be deemed amended as necessary to conform to Applicable Laws.
- 5.5 <u>Successors and Assigns</u>. The Company may assign any of its rights under this Agreement to single or multiple assignees, and this Agreement will inure to the benefit of the successors and assigns of the Company. Subject to the restrictions on transfer set forth in this Agreement or the Plan, this Agreement will be binding upon and inure to the benefit of the heirs, legatees, legal representatives, successors and assigns of the parties hereto.

- 5.6 <u>Limitations Applicable to Section 16 Persons</u>. Notwithstanding any other provision of the Plan or this Agreement, if Participant is subject to Section 16 of the Exchange Act, the Plan, the Grant Notice, this Agreement and the Restricted Shares will be subject to any additional limitations set forth in any applicable exemptive rule under Section 16 of the Exchange Act (including any amendment to Rule 16b-3) that are requirements for the application of such exemptive rule. To the extent Applicable Laws permit, this Agreement will be deemed amended as necessary to conform to such applicable exemptive rule.
- 5.7 Entire Agreement. The Plan, the Grant Notice and this Agreement (including any exhibit hereto) constitute the entire agreement of the parties and supersede in their entirety all prior undertakings and agreements of the Company and Participant with respect to the subject matter hereof.
- 5.8 <u>Agreement Severable</u>. In the event that any provision of the Grant Notice or this Agreement is held illegal or invalid, the provision will be severable from, and the illegality or invalidity of the provision will not be construed to have any effect on, the remaining provisions of the Grant Notice or this Agreement.
- 5.9 <u>Limitation on Participant's Rights</u>. Participation in the Plan confers no rights or interests other than as herein provided. This Agreement creates only a contractual obligation on the part of the Company as to amounts payable and may not be construed as creating a trust. Neither the Plan nor any underlying program, in and of itself, has any assets. Participant will have only the rights of a general unsecured creditor of the Company with respect to amounts credited and benefits payable, if any, with respect to the Award.
- 5.10 Not a Contract of Employment. Nothing in the Plan, the Grant Notice or this Agreement confers upon Participant any right to continue in the employ or service of the Company or any Subsidiary or interferes with or restricts in any way the rights of the Company and its Subsidiaries, which rights are hereby expressly reserved, to discharge or terminate the services of Participant at any time for any reason whatsoever, with or without cause, except to the extent expressly provided otherwise in a written agreement between the Company or a Subsidiary and Participant.
- 5.11 <u>Counterparts</u>. The Grant Notice may be executed in one or more counterparts, including by way of any electronic signature, subject to Applicable Law, each of which will be deemed an original and all of which together will constitute one instrument.

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#### MEIRAGTX HOLDINGS PLC

#### NON-EMPLOYEE DIRECTOR COMPENSATION PROGRAM

Non-employee members of the board of directors (the "Board") of MeiraGTx Holdings plc (the "Company") shall receive cash and equity compensation as set forth in this Non-Employee Director Compensation Program (this "Program"). The cash and equity compensation described in this Program shall be paid or be made, as applicable, automatically and without further action of the Board, to each member of the Board who is not an employee of the Company or any parent or subsidiary of the Company (each, a "Non-Employee Director") who is entitled to receive such cash or equity compensation, unless such Non-Employee Director declines the receipt of such cash or equity compensation by written notice to the Company. This Program shall remain in effect until it is revised or rescinded by further action of the Board. This Program may be amended, modified or terminated by the Board at any time in its sole discretion. The terms and conditions of this Program shall supersede any prior cash and/or equity compensation arrangements for service as a member of the Board between the Company and any of its Non-Employee Directors. This Program shall become effective on the date of the effectiveness of the Company's Registration Statement on Form S-1 relating to the initial public offering of ordinary shares (the "Effective Date").

#### I. CASH COMPENSATION

- A. Annual Retainers. Each Non-Employee Director shall receive an annual retainer of \$25,000 for service on the Board.
- B. Additional Annual Retainers. In addition, each Non-Employee Director shall receive the following annual retainers:
- 1. Chairman of the Board or Lead Independent Director. A Non-Employee Director serving as Chairman of the Board or Lead Independent Director shall receive an additional annual retainer of \$25,000 for such service.
- 2. *Audit Committee.* A Non-Employee Director serving as Chairperson of the Audit Committee shall receive an additional annual retainer of \$15,000 for such service. A Non-Employee Director serving as a member other than the Chairperson of the Audit Committee shall receive an additional annual retainer of \$5,000 for such service.
- 3. *Compensation Committee*. A Non-Employee Director serving as Chairperson of the Compensation Committee shall receive an additional annual retainer of \$10,000 for such service. A Non-Employee Director serving as a member other than the Chairperson of the Compensation Committee shall receive an additional annual retainer of \$5,000 for such service.
- 4. *Nominating and Corporate Governance Committee*. A Non-Employee Director serving as Chairperson of the Nominating and Corporate Governance Committee shall receive an additional annual retainer of \$10,000 for such service. A Non-Employee Director serving as a member other than the Chairperson of the Nominating and Corporate Governance Committee shall receive an additional annual retainer of \$5,000 for such service.

C. <u>Payment of Retainers</u>. The annual retainers described in Sections I(A) and I(B) shall be earned on a quarterly basis based on a calendar quarter and shall be paid in cash by the Company in arrears not later than the fifteenth day following the end of each calendar quarter. In the event a Non-Employee Director does not serve as a Non-Employee Director, or in the applicable positions described in Section I(B), for an entire calendar quarter, the retainer paid to such Non-Employee Director shall be prorated for the portion of such calendar quarter actually served as a Non-Employee Director, or in such position, as applicable.

#### II. EQUITY COMPENSATION

Non-Employee Directors shall be granted the equity awards described below. The awards described below shall be granted under and shall be subject to the terms and provisions of the Company's 2018 Incentive Award Plan or any other applicable Company equity incentive plan then-maintained by the Company (the "*Equity Plan*") and shall be granted subject to award agreements, including attached exhibits, in substantially the form approved by the Board. All applicable terms of the Equity Plan apply to this Program as if fully set forth herein, and all grants of options hereby are subject in all respects to the terms of the Equity Plan and the applicable award agreement.

- A. <u>Initial Awards</u>. Each Non-Employee Director who is initially elected or appointed to the Board after the Effective Date shall receive an option to purchase 50,000 ordinary shares of the Company on the date of such initial election or appointment. The awards described in this Section II(A) shall be referred to as "*Initial Awards*." No Non-Employee Director shall be granted more than one Initial Award.
- B. <u>Subsequent Awards</u>. A Non-Employee Director who (i) has been serving as a Non-Employee Director on the Board for at least six months as of the date of any annual meeting of the Company's shareholders after the Effective Date and (ii) will continue to serve as a Non-Employee Director immediately following such meeting, shall be automatically granted an option to purchase 25,000 ordinary shares of the Company on the date of such annual meeting. The awards described in this Section II(B) shall be referred to as "*Subsequent Awards*." For the avoidance of doubt, a Non-Employee Director elected for the first time to the Board at an annual meeting of the Company's shareholders shall only receive an Initial Award in connection with such election, and shall not receive any Subsequent Award on the date of such meeting as well.
- C. <u>Termination of Employment of Employee Directors</u>. Members of the Board who are employees of the Company or any parent or subsidiary of the Company who subsequently terminate their employment with the Company and any parent or subsidiary of the Company and remain on the Board will not receive an Initial Award pursuant to Section II(A) above, but to the extent that they are otherwise entitled, will receive, after termination from employment with the Company and any parent or subsidiary of the Company, Subsequent Awards as described in Section II(B) above.

#### D. Terms of Awards Granted to Non-Employee Directors

- 1. *Exercise Price*. The per share exercise price of each option granted to a Non-Employee Director shall equal the Fair Market Value (as defined in the Equity Plan) of an ordinary share on the date the option is granted.
- 2. Vesting. Each Initial Award shall vest and become exercisable in thirty-six (36) substantially equal monthly installments following the date of grant, such that the Initial Award shall be fully vested on the third anniversary of the date of grant, subject to the Non-Employee Director continuing in service as a Non-Employee Director through each such vesting date. Each Subsequent Award shall vest and become exercisable on the earlier of the first anniversary of the date of grant or the day immediately prior to the date of the next annual meeting of the Company's shareholders occurring after the date of grant, in either case subject to the Non-Employee Director continuing in service on the Board as a Non-Employee Director through each such vesting date. Unless the Board otherwise determines, any portion of an Initial Award or Subsequent Award which is unvested or unexercisable at the time of a Non-Employee Director's termination of service on the Board as a Non-Employee Director shall be immediately forfeited upon such termination of service and shall not thereafter become vested and exercisable. All of a Non-Employee Director's Initial Awards and Subsequent Awards shall vest in full immediately prior to the occurrence of a Change in Control (as defined in the Equity Plan), to the extent outstanding at such time.
- 3. *Term.* The maximum term of each option granted to a Non-Employee Director hereunder shall be ten (10) years from the date the option is granted.

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#### MEIRAGTX HOLDINGS PLC

#### INDEMNIFICATION AGREEMENT

THIS INDEMNIFICATION AGREEMENT (the "*Agreement*") is made and entered into on \_\_\_\_\_\_\_, 20[18] between MeiraGTx Holdings plc, a Cayman Islands exempted company (the "*Company*"), and [Name] ("*Indemnitee*").

# WITNESSETH THAT:

WHEREAS, highly competent persons have become more reluctant to serve corporations as directors, officers or in other capacities unless they are provided with adequate protection through insurance or adequate indemnification against inordinate risks of claims and actions against them arising out of their service to and activities on behalf of the corporation;

WHEREAS, the Board of Directors of the Company (the "**Board**") has determined that, in order to attract and retain qualified individuals, the Company will attempt to maintain on an ongoing basis, at its sole expense, liability insurance to protect persons serving the Company and its subsidiaries from certain liabilities. Although the furnishing of such insurance has been a customary and widespread practice among business enterprises, the Company believes that, given current market conditions and trends, such insurance may be available to it in the future only at higher premiums and with more exclusions. At the same time, directors, officers, and other persons in service to corporations or business enterprises are being increasingly subjected to expensive and time-consuming litigation relating to, among other things, matters that traditionally would have been brought only against the Company or business enterprise itself. The articles of association of the Company provides for the indemnification of the officers and directors of the Company. The indemnification provisions in the Company's articles of association are not exclusive, and thereby contracts may be entered into between the Company and members of the Board, officers and other persons with respect to indemnification;

WHEREAS, the uncertainties relating to such insurance and to indemnification have increased the difficulty of attracting and retaining such persons;

WHEREAS, the Board has determined that the increased difficulty in attracting and retaining such persons is detrimental to the best interests of the Company's shareholders and that the Company should act to assure such persons that there will be increased certainty of such protection in the future;

WHEREAS, it is reasonable, prudent and necessary for the Company contractually to obligate itself to indemnify, and to advance expenses on behalf of, such persons to the fullest extent permitted by applicable law so that they will serve or continue to serve the Company free from undue concern that they will not be so indemnified:

WHEREAS, this Agreement is a supplement to and in furtherance of the articles of association of the Company and any resolutions adopted pursuant thereto, and shall not be deemed a substitute therefor, nor to diminish or abrogate any rights of Indemnitee thereunder; [and]

WHEREAS, Indemnitee does not regard the protection available under the Company's and articles of association and insurance as adequate in the present circumstances, and may not be willing to serve as an officer or director without adequate protection, and the Company desires Indemnitee to serve in such capacity. Indemnitee is willing to serve, continue to serve and to take on additional service for or on behalf of the Company on the condition that he be so indemnified; [and]

[WHEREAS, Indemnitee has certain rights to indemnification and/or insurance provided by [NAME] which Indemnitee and [NAME] intend to be secondary to the primary obligation of the Company to indemnify Indemnitee as provided herein, with the Company's acknowledgement and agreement to the foregoing being a material condition to Indemnitee's willingness to serve on the Board;]

NOW, THEREFORE, in consideration of Indemnitee's agreement to serve as an officer or director from and after the date hereof, the parties hereto agree as follows:

- 1. <u>Indemnity of Indemnitee</u>. The Company hereby agrees to hold harmless and indemnify Indemnitee to the fullest extent permitted by law, as such may be amended from time to time. In furtherance of the foregoing indemnification, and without limiting the generality thereof:
- (a) <u>Proceedings Other Than Proceedings by or in the Right of the Company.</u> Indemnitee shall be entitled to the rights of indemnification provided in this <u>Section I(a)</u> if, by reason of his Corporate Status (as hereinafter defined), the Indemnitee is, or is threatened to be made, a party to or participant in any Proceeding (as hereinafter defined) other than a Proceeding by or in the right of the Company. Pursuant to this <u>Section 1(a)</u>, Indemnitee shall be indemnified against all Expenses (as hereinafter defined), judgments, penalties, fines and amounts paid in settlement actually and reasonably incurred by him, or on his behalf, in connection with such Proceeding or any claim, issue or matter therein, if the Indemnitee acted in good faith and in a manner the Indemnitee reasonably believed to be in or not opposed to the best interests of the Company, and with respect to any criminal Proceeding, had no reasonable cause to believe the Indemnitee's conduct was unlawful.
- (b) <u>Proceedings by or in the Right of the Company.</u> Indemnitee shall be entitled to the rights of indemnification provided in this <u>Section 1(b)</u> if, by reason of his Corporate Status, the Indemnitee is, or is threatened to be made, a party to or participant in any Proceeding brought by or in the right of the Company. Pursuant to this <u>Section 1(b)</u>, Indemnitee shall be indemnified against all Expenses actually and reasonably incurred by the Indemnitee, or on the Indemnitee's behalf, in connection with such Proceeding if the Indemnitee acted in good faith and in a manner the Indemnitee reasonably believed to be in or not opposed to the best interests of the Company; provided, however, if applicable law so provides, no indemnification against such Expenses shall be made in respect of any claim, issue or matter in such Proceeding as to which Indemnitee shall have been adjudged to be liable to the Company unless and to the extent that the Grand Court of the Cayman Islands shall determine that such indemnification may be made.

(c) <u>Indemnification for Expenses of a Party Who is Wholly or Partly Successful</u>. Notwithstanding any other provision of this Agreement, to the extent that Indemnitee is, by reason of his Corporate Status, a party to and is successful, on the merits or otherwise, in any Proceeding, he shall be indemnified to the maximum extent permitted by law, as such may be amended from time to time, against all Expenses actually and reasonably incurred by him or on his behalf in connection therewith. If Indemnitee is not wholly successful in such Proceeding but is successful, on the merits or otherwise, as to one or more but less than all claims, issues or matters in such Proceeding, the Company shall indemnify Indemnitee against all Expenses actually and reasonably incurred by him or on his behalf in connection with each successfully resolved claim, issue or matter. For purposes of this Section and without limitation, the termination of any claim, issue or matter in such a Proceeding by dismissal, with or without prejudice, shall be deemed to be a successful result as to such claim, issue or matter.

(d) [Indemnification of Appointing Shareholder. If (i) Indemnitee is or was affiliated with one or more venture capital funds that has invested in the Company (an "Appointing Shareholder"), and (ii) the Appointing Shareholder is, or is threatened to be made, a party to or a participant in any Proceeding relating to or arising by reason of Appointing Shareholder's position as a shareholder of, or lender to, the Company, or Appointing Shareholder's appointment of or affiliation with Indemnitee or any other director, including without limitation any alleged misappropriation of a Company asset or corporate opportunity, any claim of misappropriation or infringement of intellectual property relating to the Company, any alleged false or misleading statement or omission made by the Company (or on its behalf) or its employees or agents, or any allegation of inappropriate control or influence over the Company or its Board members, officers, equity holders or debt holders, then the Appointing Shareholder will be entitled to indemnification hereunder for Expenses to the same extent as Indemnitee, and the terms of this Agreement as they relate to procedures for indemnification of Indemnitee and advancement of Expenses shall apply to any such indemnification of Appointing Shareholder.

The rights provided to the Appointing Shareholder under this Section 1(d) shall (i) be suspended during any period during which the Appointing Shareholder does not have a representative on the Company's Board and (ii) terminate on an initial public offering of the Company's Ordinary Shares; provided, however, that in the event of any such suspension or termination, the Appointing Shareholder's rights to indemnification will not be suspended or terminated with respect to any Proceeding based in whole or in part on facts and circumstances occurring at any time prior to such suspension or termination regardless of whether the Proceeding arises before or after such suspension or termination. The Company and Indemnitee agree that the Appointing Shareholder is an express third party beneficiary of the terms of this Section 1(d).

Any Appointing Shareholder not being a party to this Agreement may enforce any rights granted to it pursuant to this Agreement in its own right as if it were a party to this Agreement. Except as expressly provided in the previous sentence, a person who is not a party to this Agreement shall not have any rights under the Contracts (Rights of Third Parties) Law (as amended) to enforce any term of this Agreement. Notwithstanding any term of this Agreement, the consent of or notice to any person who is not a party to this Agreement shall not be required for any termination, rescission or agreement to any variation, waiver, assignment, novation, release or settlement under this Agreement at any time.]

2. Additional Indemnity. In addition to, and without regard to any limitations on, the indemnification provided for in Section 1 of this Agreement, the Company shall and hereby does indemnify and hold harmless Indemnitee against all Expenses, judgments, penalties, fines and amounts paid in settlement actually and reasonably incurred by him or on his behalf if, by reason of his Corporate Status, he is, or is threatened to be made, a party to or participant in any Proceeding (including a Proceeding by or in the right of the Company), including, without limitation, all liability arising out of the negligence or active or passive wrongdoing of Indemnitee. The only limitation that shall exist upon the Company's obligations pursuant to this Agreement shall be that the Company shall not be obligated to make any payment to Indemnitee that is finally determined (under the procedures, and subject to the presumptions, set forth in Sections 6 and 7 hereof) to be unlawful or for claims arising from the Indemnitee's dishonesty, willful default or fraud.

#### 3. Contribution.

(a) Whether or not the indemnification provided in  $\underline{Sections\ 1}$  and  $\underline{2}$  hereof is available, in respect of any threatened, pending or completed action, suit or proceeding in which the Company is jointly liable with Indemnitee (or would be if joined in such action, suit or proceeding), the Company shall pay, in the first instance, the entire amount of any judgment or settlement of such action, suit or proceeding without requiring Indemnitee to contribute to such payment and the Company hereby waives and relinquishes any right of contribution it may have against Indemnitee. The Company shall not enter into any settlement of any action, suit or proceeding in which the Company is jointly liable with Indemnitee (or would be if joined in such action, suit or proceeding) unless such settlement provides for a full and final release of all claims asserted against Indemnitee.

(b) Without diminishing or impairing the obligations of the Company set forth in the preceding subparagraph, if, for any reason, Indemnitee shall elect or be required to pay all or any portion of any judgment or settlement in any threatened, pending or completed action, suit or proceeding in which the Company is jointly liable with Indemnitee (or would be if joined in such action, suit or proceeding), the Company shall contribute to the amount of Expenses, judgments, fines and amounts paid in settlement actually and reasonably incurred and paid or payable by Indemnitee in proportion to the relative benefits received by the Company and all officers, directors or employees of the Company, other than Indemnitee, who are jointly liable with Indemnitee (or would be if joined in such action, suit or proceeding), on the one hand, and Indemnitee, on the other hand, from the transaction or events from which such action, suit or proceeding arose; provided, however, that the proportion determined on the basis of relative benefit may, to the extent necessary to conform to law, be further adjusted by reference to the relative fault of the Company and all officers, directors or employees of the Company other than Indemnitee who are jointly liable with Indemnitee (or would be if joined in such action, suit or proceeding), on the one hand, and Indemnitee, on the other hand, in connection with the transaction or events that resulted in such expenses, judgments, fines or settlement amounts, as well as any other equitable considerations which applicable law may require to be considered. The relative fault of the Company and all officers, directors or employees of the Company, other than Indemnitee, who are jointly liable with Indemnitee (or would be if joined in such action, suit or proceeding), on the one hand, and Indemnitee, on the other hand, shall be determined by reference to, among other things, the degree to which their actions were motivated by intent to gain personal profit or advantage, the degree to which their conduc

- (c) The Company hereby agrees to fully indemnify and hold Indemnitee harmless from any claims of contribution which may be brought by officers, directors or employees of the Company, other than Indemnitee, who may be jointly liable with Indemnitee, except for claims arising from the Indemnitee's dishonesty, willful default or fraud.
- (d) To the fullest extent permissible under applicable law, if the indemnification provided for in this Agreement is unavailable to Indemnitee for any reason whatsoever, the Company, in lieu of indemnifying Indemnitee, shall contribute to the amount incurred by Indemnitee, whether for judgments, fines, penalties, excise taxes, amounts paid or to be paid in settlement and/or for Expenses, in connection with any claim relating to an indemnifiable event under this Agreement, in such proportion as is deemed fair and reasonable in light of all of the circumstances of such Proceeding in order to reflect (i) the relative benefits received by the Company and Indemnitee as a result of the event(s) and/or transaction(s) giving cause to such Proceeding and/or (ii) the relative fault of the Company (and its directors, officers, employees and agents) and Indemnitee in connection with such event(s) and/or transaction(s).
- 4. <u>Indemnification for Expenses of a Witness</u>. Notwithstanding any other provision of this Agreement, to the extent that Indemnitee is, by reason of his Corporate Status, a witness, or is made (or asked) to respond to discovery requests, in any Proceeding to which Indemnitee is not a party, he shall be indemnified against all Expenses actually and reasonably incurred by him or on his behalf in connection therewith.
- 5. <u>Advancement of Expenses</u>. Notwithstanding any other provision of this Agreement, the Company shall advance all Expenses incurred by or on behalf of Indemnitee in connection with any Proceeding by reason of Indemnitee's Corporate Status within thirty (30) days after the receipt by the Company of a statement or statements from Indemnitee requesting such advance or advances from time to time, whether prior to or after final disposition of such Proceeding. Such statement or statements shall reasonably evidence the Expenses incurred by Indemnitee. The Indemnitee shall qualify for advances upon the execution and delivery to the Company of this Agreement, which shall constitute an undertaking by Indemnitee to repay any Expenses advanced if it shall ultimately be determined that Indemnitee is not entitled to be indemnified against such Expenses. Any advances and undertakings to repay pursuant to this Section 5 shall be unsecured and interest free.
- 6. <u>Procedures and Presumptions for Determination of Entitlement to Indemnification</u>. It is the intent of this Agreement to secure for Indemnitee rights of indemnity that are as favorable as may be permitted under the Companies Law, as amended, public policy and other applicable law of the Cayman Islands. Accordingly, the parties agree that the following procedures and presumptions shall apply in the event of any question as to whether Indemnitee is entitled to indemnification under this Agreement:
- (a) To obtain indemnification under this Agreement, Indemnitee shall submit to the Company a written request, including therein or therewith such documentation and information as is reasonably available to Indemnitee and is reasonably necessary to determine whether and to what extent Indemnitee is entitled to indemnification. The Secretary of the Company shall, promptly upon receipt of such a request for indemnification, advise the Board in writing that Indemnitee has requested indemnification. Notwithstanding the foregoing, any failure of Indemnitee to provide such a request to the Company, or to provide such a request in a timely fashion, shall not relieve the Company of any liability that it may have to Indemnitee unless, and to the extent that, such failure actually and materially prejudices the interests of the Company.

(b) Upon written request by Indemnitee for indemnification pursuant to the first sentence of Section 6(a) hereof, a determination with respect to Indemnitee's entitlement thereto shall be made in the specific case by one of the following four methods, which shall be at the election of the Board: (1) by a majority vote of the disinterested directors, provided such disinterested directors form a quorum, (2) by a committee of disinterested directors designated by a majority vote of the disinterested directors, (3) if there are no disinterested directors or if the committee of disinterested directors so directs, by independent legal counsel in a written opinion to the Board, a copy of which shall be delivered to the Indemnitee, or (4) if so directed by the Board, by the shareholders of the Company by an ordinary resolution. For purposes hereof, disinterested directors are those members of the Board who are not parties to the action, suit or proceeding in respect of which indemnification is sought by Indemnitee.

(c) If the determination of entitlement to indemnification is to be made by Independent Counsel pursuant to Section 6(b) hereof, the Independent Counsel shall be selected as provided in this Section 6(c). The Independent Counsel shall be selected by the Board. Indemnitee may, within ten (10) days after such written notice of selection shall have been given, deliver to the Company a written objection to such selection; provided, however, that such objection may be asserted only on the ground that the Independent Counsel so selected does not meet the requirements of "Independent Counsel" as defined in Section 13 of this Agreement, and the objection shall set forth with particularity the factual basis of such assertion. Absent a proper and timely objection, the person so selected shall act as Independent Counsel. If a written objection is made and substantiated, the Independent Counsel selected may not serve as Independent Counsel unless and until such objection is withdrawn or a court has determined that such objection is without merit. If, within twenty (20) days after the conclusion of the Proceeding giving rise to the request for indemnification, no Independent Counsel shall have been selected and not objected to, either the Company or Indemnitee may petition the Grand Court of the Cayman Islands for resolution of any objection which shall have been made by the Indemnitee to the Company's selection of Independent Counsel and/or for the appointment as Independent Counsel of a person selected by the court or by such other person as the court shall designate, and the person with respect to whom all objections are so resolved or the person so appointed shall act as Independent Counsel under Section 6(b) hereof. The Company shall pay any and all reasonable fees and expenses of Independent Counsel incurred by such Independent Counsel in connection with acting pursuant to Section 6(b) hereof, and the Company shall pay all reasonable fees and expenses incident to the procedures of this Section 6(c), regardless of the

(d) In making a determination with respect to entitlement to indemnification hereunder, the person or persons or entity making such determination shall presume that Indemnitee is entitled to indemnification under this Agreement. Anyone seeking to overcome this presumption shall have the burden of proof by clear and convincing evidence. Neither the failure of the Company (including by its directors or independent legal counsel) to have made a determination prior to the commencement of any action pursuant to this Agreement that indemnification is proper in the circumstances because Indemnitee has met the applicable

standard of conduct, nor an actual determination by the Company (including by its directors or independent legal counsel) that Indemnitee has not met such applicable standard of conduct, shall be a defense to the action or create a presumption that Indemnitee has not met the applicable standard of conduct.

(e) Indemnitee shall be deemed to have acted in good faith if Indemnitee's action is based on the records or books of account of the Enterprise (as hereinafter defined), including financial statements, or on information supplied to Indemnitee by the officers of the Enterprise in the course of their duties, or on the advice of legal counsel for the Enterprise or on information or records given or reports made to the Enterprise by an independent certified public accountant or by an appraiser or other expert selected with reasonable care by the Enterprise. In addition, the knowledge and/or actions, or failure to act, of any director, officer, agent or employee of the Enterprise shall not be imputed to Indemnitee for purposes of determining the right to indemnification under this Agreement. Whether or not the foregoing provisions of this Section 6(e) are satisfied, it shall in any event be presumed that Indemnitee has at all times acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the Company. Anyone seeking to overcome this presumption shall have the burden of proof by clear and convincing evidence.

(f) If the person, persons or entity empowered or selected under Section 6 to determine whether Indemnitee is entitled to indemnification shall not have made a determination within sixty (60) days after the conclusion of the Proceeding giving rise to the request for indemnification, the requisite determination of entitlement to indemnification shall be deemed to have been made and Indemnitee shall be entitled to such indemnification absent (i) a misstatement by Indemnitee of a material fact, or an omission of a material fact necessary to make Indemnitee's statement not materially misleading, in connection with the request for indemnification, or (ii) a prohibition of such indemnification under applicable law; provided, however, that such sixty (60)-day period may be extended for a reasonable time, not to exceed an additional thirty (30) days, if the person, persons or entity making such determination with respect to entitlement to indemnification in good faith requires such additional time to obtain or evaluate documentation and/or information relating thereto; and provided, further, that the foregoing provisions of this Section 6(f) shall not apply if the determination of entitlement to indemnification is to be made by the shareholders pursuant to Section 6(b) of this Agreement and if (A) within fifteen (15) days after the conclusion of the Proceeding giving rise to the request for indemnification, the Board or the Disinterested Directors, if appropriate, resolve to submit such determination to the shareholders for their consideration at an annual meeting thereof to be held within seventy-five (75) days after such resolution and such determination is made thereat, or (B) a special meeting of shareholders is called within fifteen (15) days after such resolution and such meeting is held for such purpose within sixty (60) days after having been so called and such determination is made thereat.

(g) Indemnitee shall cooperate with the person, persons or entity making such determination with respect to Indemnitee's entitlement to indemnification, including providing to such person, persons or entity upon reasonable advance request any documentation or information which is not privileged or otherwise protected from disclosure and which is reasonably available to Indemnitee and reasonably necessary to such determination. Any Independent Counsel, member of the Board or shareholder of the Company shall act reasonably and in good faith in making a determination regarding the Indemnitee's entitlement to

indemnification under this Agreement. Any costs or expenses (including attorneys' fees and disbursements) incurred by Indemnitee in so cooperating with the person, persons or entity making such determination shall be borne by the Company (irrespective of the determination as to Indemnitee's entitlement to indemnification) and the Company hereby indemnifies and agrees to hold Indemnitee harmless therefrom.

- (h) The Company acknowledges that a settlement or other disposition short of final judgment may be successful if it permits a party to avoid expense, delay, distraction, disruption and uncertainty. In the event that any action, claim or proceeding to which Indemnitee is a party is resolved in any manner other than by adverse judgment against Indemnitee (including, without limitation, settlement of such action, claim or proceeding with or without payment of money or other consideration) it shall be presumed that Indemnitee has been successful on the merits or otherwise in such action, suit or proceeding. Anyone seeking to overcome this presumption shall have the burden of proof by clear and convincing evidence.
- (i) The termination of any Proceeding or of any claim, issue or matter therein, by judgment, order, settlement or conviction, or upon a plea of nolo contendere or its equivalent, shall not (except as otherwise expressly provided in this Agreement) of itself adversely affect the right of Indemnitee to indemnification or create a presumption that Indemnitee did not act in good faith and in a manner which he reasonably believed to be in or not opposed to the best interests of the Company or, with respect to any criminal Proceeding, that Indemnitee had reasonable cause to believe that his conduct was unlawful.

#### 7. Remedies of Indemnitee.

- (a) In the event that (i) a determination is made pursuant to Section 6 of this Agreement that Indemnitee is not entitled to indemnification under this Agreement, (ii) advancement of Expenses is not timely made pursuant to Section 5 of this Agreement, (iii) no determination of entitlement to indemnification is made pursuant to Section 6(b) of this Agreement within ninety (90) days after the conclusion of the Proceeding giving rise to the request for indemnification, (iv) payment of indemnification required by Section 4 is not made pursuant to this Agreement within thirty (30) days after receipt by the Company of a written request therefor or (v) payment of indemnification is not made within ten (10) days after a determination has been made that Indemnitee is entitled to indemnification or such determination is deemed to have been made pursuant to Section 6 of this Agreement, Indemnitee shall be entitled to an adjudication in Grand Court of the Cayman Islands of Indemnitee's entitlement to such indemnification. Indemnitee shall commence such proceeding seeking an adjudication within one hundred eighty (180) days following the date on which Indemnitee first has the right to commence such proceeding pursuant to this Section 7(a). The Company shall not oppose Indemnitee's right to seek any such adjudication.
- (b) In the event that a determination shall have been made pursuant to <u>Section 6(b)</u> of this Agreement that Indemnitee is not entitled to indemnification, any judicial proceeding commenced pursuant to this <u>Section 7</u> shall be conducted in all respects as a de novo trial on the merits, and Indemnitee shall not be prejudiced by reason of the adverse determination under <u>Section 6(b)</u>.

- (c) If a determination shall have been made pursuant to <u>Section 6(b)</u> of this Agreement that Indemnitee is entitled to indemnification, the Company shall be bound by such determination in any judicial proceeding commenced pursuant to this <u>Section 7</u>, absent (i) a misstatement by Indemnitee of a material fact, or an omission of a material fact necessary to make Indemnitee's misstatement not materially misleading in connection with the application for indemnification, or (ii) a prohibition of such indemnification under applicable law.
- (d) In the event that Indemnitee, pursuant to this <u>Section 7</u>, seeks a judicial adjudication of his rights under, or to recover damages for breach of, this Agreement, or to recover under any directors' and officers' liability insurance policies maintained by the Company, the Company shall pay on his behalf, in advance, any and all expenses (of the types described in the definition of Expenses in <u>Section 13</u> of this Agreement) actually and reasonably incurred by him in such judicial adjudication, regardless of whether Indemnitee ultimately is determined to be entitled to such indemnification, advancement of expenses or insurance recovery.
- (e) The Company shall be precluded from asserting in any judicial proceeding commenced pursuant to this Section 7 that the procedures and presumptions of this Agreement are not valid, binding and enforceable and shall stipulate in any such court that the Company is bound by all the provisions of this Agreement. The Company shall indemnify Indemnitee against any and all Expenses and, if requested by Indemnitee, shall (within ten (10) days after receipt by the Company of a written request therefore) advance, to the extent not prohibited by law, such expenses to Indemnitee, which are incurred by Indemnitee in connection with any action brought by Indemnitee for indemnification or advance of Expenses from the Company under this Agreement or under any directors' and officers' liability insurance policies maintained by the Company, regardless of whether Indemnitee ultimately is determined to be entitled to such indemnification, advancement of Expenses or insurance recovery, as the case may be.
- (f) Notwithstanding anything in this Agreement to the contrary, no determination as to entitlement to indemnification under this Agreement shall be required to be made prior to the final disposition of the Proceeding.
  - 8. Non-Exclusivity; Survival of Rights; Insurance; Primacy of Indemnification; Subrogation.
- (a) The rights of indemnification as provided by this Agreement shall not be deemed exclusive of any other rights to which Indemnitee may at any time be entitled under applicable law, the articles of association, any agreement, a vote of shareholders, a resolution of directors of the Company, or otherwise. No amendment, alteration or repeal of this Agreement or of any provision hereof shall limit or restrict any right of Indemnitee under this Agreement in respect of any action taken or omitted by such Indemnitee in his Corporate Status prior to such amendment, alteration or repeal. To the extent that a change in the Companies Law, as amended, of the Cayman Islands, whether by statute or judicial decision, permits greater indemnification than would be afforded currently under the articles of association of the Company and this Agreement, it is the intent of the parties hereto that Indemnitee shall enjoy by this Agreement the greater benefits so afforded by such change. No right or remedy herein conferred is intended to be exclusive of any other right or remedy, and every other right and remedy shall be cumulative and in addition to every other right and remedy given hereunder or now or hereafter existing at law or in equity or otherwise. The assertion or employment of any right or remedy hereunder, or otherwise, shall not prevent the concurrent assertion or employment of any other right or remedy.

(b) To the extent that the Company maintains an insurance policy or policies providing liability insurance for directors, officers, employees, or agents or fiduciaries of the Company or of any other corporation, partnership, joint venture, trust, employee benefit plan or other enterprise that such person serves at the request of the Company, Indemnitee shall be covered by such policy or policies in accordance with its or their terms to the maximum extent of the coverage available for any director, officer, employee, agent or fiduciary under such policy or policies. If, at the time of the receipt of a notice of a claim pursuant to the terms hereof, the Company has directors' and officers' liability insurance in effect, the Company shall give prompt notice of the commencement of such proceeding to the insurers in accordance with the procedures set forth in the respective policies. The Company shall thereafter take all necessary or desirable action to cause such insurers to pay, on behalf of the Indemnitee, all amounts payable as a result of such proceeding in accordance with the terms of such policies.

(c) [The Company hereby acknowledges that Indemnitee has certain rights to indemnification, advancement of expenses and/or insurance provided by [•] and certain of its affiliates (collectively, the "Fund Indemnitors"). The Company hereby agrees (i) that it is the indemnitor of first resort (i.e., its obligations to Indemnitee are primary and any obligation of the Fund Indemnitors to advance expenses or to provide indemnification for the same expenses or liabilities incurred by Indemnitee are secondary), (ii) that it shall be required to advance the full amount of expenses incurred by Indemnitee and shall be liable for the full amount of all Expenses, judgments, penalties, fines and amounts paid in settlement to the extent legally permitted and as required by the terms of this Agreement and the [memorandum and articles of association] of the Company (or any other agreement between the Company and Indemnitee), without regard to any rights Indemnitee may have against the Fund Indemnitors, and, (iii) that it irrevocably waives, relinquishes and releases the Fund Indemnitors from any and all claims against the Fund Indemnitors for contribution, subrogation or any other recovery of any kind in respect thereof. The Company further agrees that no advancement or payment by the Fund Indemnitors on behalf of Indemnitee with respect to any claim for which Indemnitee has sought indemnification from the Company shall affect the foregoing and the Fund Indemnitors shall have a right of contribution and/or be subrogated to the extent of such advancement or payment to all of the rights of recovery of Indemnitee against the Company. The Company and Indemnitee agree that the Fund Indemnitors are express third party beneficiaries of the terms of this Section 8(c). Any Fund Indemnitor not being a party to this Agreement may enforce any rights granted to it pursuant to this Agreement in its own right as if it were a party to this Agreement. Except as expressly provided in the previous sentence, a person who is not a party to this Agreement shall not have any rights under the Contracts (Rights of Third Parties) Law (as amended) to enforce any term of this Agreement. Notwithstanding any term of this Agreement, the consent of or notice to any person who is not a party to this Agreement shall not be required for any termination, rescission or agreement to any variation, waiver, assignment, novation, release or settlement under this Agreement at any time.]

(d) [Except as provided in paragraph (c) above,] in the event of any payment under this Agreement, the Company shall be subrogated to the extent of such payment to all of the rights of recovery of Indemnitee [(other than against the Fund Indemnitors)], who shall execute all papers required and take all action necessary to secure such rights, including execution of such documents as are necessary to enable the Company to bring suit to enforce such rights.

- (e) [Except as provided in paragraph (c) above,] the Company shall not be liable under this Agreement to make any payment of amounts otherwise indemnifiable hereunder if and to the extent that Indemnitee has otherwise actually received such payment under any insurance policy, contract, agreement or otherwise.
- (f) [Except as provided in paragraph (c) above,] the Company's obligation to indemnify or advance Expenses hereunder to Indemnitee who is or was serving at the request of the Company as a director, officer, employee or agent of any other corporation, partnership, joint venture, trust, employee benefit plan or other enterprise shall be reduced by any amount Indemnitee has actually received as indemnification or advancement of expenses from such other corporation, partnership, joint venture, trust, employee benefit plan or other enterprise.
- 9. Exception to Right of Indemnification. Notwithstanding any provision in this Agreement, the Company shall not be obligated under this Agreement to make any indemnity in connection with any claim made against Indemnitee:
- (a) for which payment has actually been made to or on behalf of Indemnitee under any insurance policy or other indemnity provision, except with respect to any excess beyond the amount paid under any insurance policy or other indemnity provision[, provided, that the foregoing shall not affect the rights of Indemnitee or the Fund Indemnitors set forth in Section 8(c) above]; or
- (b) for an accounting of profits made from the purchase and sale (or sale and purchase) by Indemnitee of securities of the Company within the meaning of Section 16(b) of the Securities Exchange Act of 1934, as amended, or similar provisions of any applicable law; or
- (c) in connection with any Proceeding (or any part of any Proceeding) initiated by Indemnitee, including any Proceeding (or any part of any Proceeding) initiated by Indemnitee against the Company or its directors, officers, employees or other indemnitees, unless (i) the Board authorized the Proceeding (or any part of any Proceeding) prior to its initiation or (ii) the Company provides the indemnification, in its sole discretion, pursuant to the powers vested in the Company under applicable law.
- 10. <u>Duration of Agreement</u>. All agreements and obligations of the Company contained herein shall continue during the period Indemnitee is an officer or director of the Company (or is or was serving at the request of the Company as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise) and shall continue thereafter so long as Indemnitee shall be subject to any Proceeding (or any proceeding commenced under <u>Section 7</u> hereof) by reason of his Corporate Status, whether or not he is acting or serving in any such capacity at the time any liability or expense is incurred for which indemnification can be provided under this Agreement. This Agreement shall be binding upon and inure to the benefit of and be enforceable by the parties hereto and their respective successors (including any direct or indirect successor by purchase, merger, consolidation or otherwise to all or substantially all of the business or assets of the Company), assigns, spouses, heirs, executors and personal and legal representatives.

11. <u>Security</u>. To the extent requested by Indemnitee and approved by the Board, the Company may at any time and from time to time provide security to Indemnitee for the Company's obligations hereunder through an irrevocable bank line of credit, funded trust or other collateral. Any such security, once provided to Indemnitee, may not be revoked or released without the prior written consent of the Indemnitee.

#### 12. Enforcement.

- (a) The Company expressly confirms and agrees that it has entered into this Agreement and assumes the obligations imposed on it hereby in order to induce Indemnitee to serve as an officer or director of the Company, and the Company acknowledges that Indemnitee is relying upon this Agreement in serving as an officer or director of the Company.
- (b) This Agreement constitutes the entire agreement between the parties hereto with respect to the subject matter hereof and supersedes all prior agreements and understandings, oral, written and implied, between the parties hereto with respect to the subject matter hereof.
- (c) The Company shall not seek from a court, or agree to, an order which would have the effect of prohibiting or limiting the Indemnitee's rights to receive advancement of expenses under this Agreement.

# 13. <u>Definitions</u>. For purposes of this Agreement:

- (a) "Corporate Status" describes the status of a person who is or was a director, officer, employee, agent or fiduciary of the Company or of any other corporation, partnership, joint venture, trust, employee benefit plan or other enterprise that such person is or was serving at the express written request of the Company.
- (b) "Disinterested Director" means a director of the Company who is not and was not a party to the Proceeding in respect of which indemnification is sought by Indemnitee.
- (c) "*Enterprise*" shall mean the Company and any other corporation, partnership, joint venture, trust, employee benefit plan or other enterprise that Indemnitee is or was serving at the express written request of the Company as a director, officer, employee, agent or fiduciary.
- (d) "Expenses" shall include all reasonable attorneys' fees, retainers, court costs, transcript costs, fees of experts, witness fees, travel expenses, duplicating costs, printing and binding costs, telephone charges, postage, delivery service fees and all other disbursements or expenses of the types customarily incurred in connection with prosecuting, defending, preparing to prosecute or defend, investigating, participating, or being or preparing to be a witness in a Proceeding, or responding to, or objecting to, a request to provide discovery in any Proceeding. Expenses also shall include Expenses incurred in connection with any appeal

resulting from any Proceeding and any taxes imposed on the Indemnitee as a result of the actual or deemed receipt of any payments under this Agreement, including without limitation the premium, security for, and other costs relating to any cost bond, supersede as bond, or other appeal bond or its equivalent. Expenses, however, shall not include amounts paid in settlement by Indemnitee or the amount of judgments or fines against Indemnitee.

- (e) "Independent Counsel" means a law firm, or a member of a law firm, that is experienced in matters of corporation law and neither presently is, nor in the past five years has been, retained to represent: (i) the Company or Indemnitee in any matter material to either such party (other than with respect to matters concerning Indemnitee under this Agreement, or of other indemnitees under similar indemnification agreements), or (ii) any other party to the Proceeding giving rise to a claim for indemnification hereunder. Notwithstanding the foregoing, the term "Independent Counsel" shall not include any person who, under the applicable standards of professional conduct then prevailing, would have a conflict of interest in representing either the Company or Indemnitee in an action to determine Indemnitee's rights under this Agreement. The Company agrees to pay the reasonable fees of the Independent Counsel referred to above and to fully indemnify such counsel against any and all Expenses, claims, liabilities and damages arising out of or relating to this Agreement or its engagement pursuant hereto.
- (f) "*Proceeding*" includes any threatened, pending or completed action, suit, arbitration, alternate dispute resolution mechanism, investigation, inquiry, administrative hearing or any other actual, threatened or completed proceeding, whether brought by or in the right of the Company or otherwise and whether civil, criminal, administrative or investigative, in which Indemnitee was, is or will be involved as a party or otherwise, by reason of his or her Corporate Status, by reason of any action taken by him or of any inaction on his part while acting in his or her Corporate Status; in each case whether or not he is acting or serving in any such capacity at the time any liability or expense is incurred for which indemnification can be provided under this Agreement; including one pending on or before the date of this Agreement, but excluding one initiated by an Indemnitee pursuant to Section 7 of this Agreement to enforce his rights under this Agreement.
- 14. <u>Severability</u>. The invalidity or unenforceability of any provision hereof shall in no way affect the validity or enforceability of any other provision. Further, the invalidity or unenforceability of any provision hereof as to either Indemnitee or Appointing Shareholder shall in no way affect the validity or enforceability of any provision hereof as to the other. Without limiting the generality of the foregoing, this Agreement is intended to confer upon Indemnitee and Appointing Shareholder indemnification rights to the fullest extent permitted by applicable laws. In the event any provision hereof conflicts with any applicable law, such provision shall be deemed modified, consistent with the aforementioned intent, to the extent necessary to resolve such conflict.
- 15. <u>Modification and Waiver</u>. No supplement, modification, termination or amendment of this Agreement shall be binding unless executed in writing by both of the parties hereto. No waiver of any of the provisions of this Agreement shall be deemed or shall constitute a waiver of any other provisions hereof (whether or not similar) nor shall such waiver constitute a continuing waiver.

- 16. <u>Notice By Indemnitee</u>. Indemnitee agrees promptly to notify the Company in writing upon being served with or otherwise receiving any summons, citation, subpoena, complaint, indictment, information or other document relating to any Proceeding or matter which may be subject to indemnification covered hereunder. The failure to so notify the Company shall not relieve the Company of any obligation which it may have to Indemnitee under this Agreement or otherwise unless and only to the extent that such failure or delay materially prejudices the Company.
- 17. Notices. All notices and other communications given or made pursuant to this Agreement shall be in writing and shall be deemed effectively given: (a) upon personal delivery to the party to be notified, (b) when sent by confirmed electronic mail or facsimile if sent during normal business hours of the recipient, and if not so confirmed, then on the next business day, (c) five (5) days after having been sent by registered or certified mail, return receipt requested, postage prepaid, or (d) one (1) day after deposit with a nationally recognized overnight courier, specifying next day delivery, with written verification of receipt. All communications shall be sent:
  - (a) To Indemnitee at the address set forth below Indemnitee signature hereto.
  - (b) To the Company at:

MeiraGTx Holdings plc 430 East 29th Street, 10th Floor New York, NY 10016 Attention: Chief Executive Officer

or to such other address as may have been furnished to Indemnitee by the Company or to the Company by Indemnitee, as the case may be.

- 18. <u>Counterparts</u>. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Counterparts may be delivered via facsimile, electronic mail (including pdf or any electronic signature complying with the Electronic Transactions Law (as amended), *e.g.*, www.docusign.com]) or any other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes.
- 19. <u>Headings</u>. The headings of the paragraphs of this Agreement are inserted for convenience only and shall not be deemed to constitute part of this Agreement or to affect the construction thereof.
- 20. Governing Law and Consent to Jurisdiction. This Agreement and the legal relations among the parties shall be governed by, and construed and enforced in accordance with, the laws of the Cayman Islands, without regard to its conflict of laws rules. The Company and Indemnitee hereby irrevocably and unconditionally (i) agree that any action or proceeding arising out of or in connection with this Agreement shall be brought only in the Grand Court of the Cayman Islands (the "Cayman Court"), and not in any other court in the Cayman Islands or any court in any other country, (ii) consent to submit to the exclusive jurisdiction of the Cayman

Court for purposes of any action or proceeding arising out of or in connection with this Agreement, (iii) waive any objection to the laying of venue of any such action or proceeding in the Cayman Court, and (iv) waive, and agree not to plead or to make, any claim that any such action or proceeding brought in the Cayman Court has been brought in an improper or inconvenient forum.

# SIGNATURE PAGE TO FOLLOW

IN WITNESS WHEREOF, the parties hereto have executed this Indemnification Agreement on and as of the day and year first above written.

# Name: Title: INDEMNITEE Name: Address:

MeiraGTx Holdings plc

Indemnification Agreement

#### **Employment Agreement**

This Employment Agreement ("Agreement") is entered into effective as of February 15th, 2016, by and between MeiraGTx LLC ("Meira"), a Delaware limited liability company, and its parent MeiraGTx Limited and subsidiaries (together, the "Company" or "MeiraGTx"), and Alexandria Forbes ("Employee").

In consideration of the mutual promises and covenants set forth herein, and other good and valuable consideration, the sufficiency of which is hereby acknowledged, the Company and Employee hereby agree as follows:

- 1. Position of Employment. Meira will employ the Employee in the position of Chief Executive Officer and President of Meira and, in that position, Employee will report directly to the Board of Directors of Meira. In the event of a conflict between this Agreement and any Company policies, procedures, and practices, the terms of this Agreement shall govern. Except as disclosed on Exhibit 1, Employee shall not undertake, either as an owner, director, shareholder, employee, or otherwise, the performance of services for compensation (actual or expected) for any other entity without the express written consent of the Board of Directors of Meira.
- 2. *Term of Employment*. Employee's employment with Meira shall begin on February 15<sup>th</sup>, 2016, and shall continue until February 15<sup>th</sup>, 2019. Unless Employee or Meira gives notice of non-renewal to the other party at least 90 days before the expiration of the 3-year initial term (or each 1- year successive term), this Agreement and Employee's employment shall be automatically renewed and extended for additional 1-year periods. During a term, Employee's employment may be terminated only in accordance with Section 4 of this Agreement.
- 3. Compensation and Benefits.

A. Base Salary. Employee shall initially be paid a base salary of \$390,000 in cash annually by Meira, to be paid in accordance with Meira's regular payroll policies but no less frequently than twice per month ("Base Salary"). Employee's Base Salary shall be increased to \$450,000 in cash annually as of the first day of the first payroll period following when the Company raises a total of \$25 million in debt or equity, or a combination thereof, in one or more private placements (including any debt or equity already raised prior to the time of this Agreement). Employee's Base Salary shall be increased to \$580,000 in cash annually as of the first day of the first payroll period following the earlier of (i) the date a registration statement for a class of the Company's securities becomes effective; or (ii) the date of a Change in Control of Meira or the Company (as defined in Section 5); or (iii) the date when the Company raises a total of \$75 million in debt or equity, in one or more private placements or strategic collaborations or corporate partnerships with another company (including any debt or equity already raised prior to the time of this Agreement). In addition, Employee's Base Salary shall be reviewed annually or periodically in accordance with Meira's normal compensation review cycle, but any increase above the amounts herein specified shall be in the sole discretion of Meira management, and nothing herein shall be deemed to require any such increase other than as set forth above; provided, however, that Employee's Base Salary shall not be reduced.

#### B. Bonuses.

- i. *Annual Bonus*. Employee's Annual Guaranteed Cash Bonus from Meira shall be 100% of Employee's Base Salary in effect at the time of payment. It shall be paid by January 15 of the following year.
- ii. *Performance Bonus*. Employee's Annual Performance Cash Bonus from Meira shall be determined by the Compensation Committee of Meira and shall be targeted at no less than 60% of salary. It shall be paid by January 15 of the following year. (For the avoidance of doubt, the Annual Performance Cash Bonus is in addition to the Annual Guaranteed Cash bonus.)
- iii. *Annual Performance Grants of Restricted Stock*. Employee shall be granted restricted stock for each year by January 15 of the following year, in amounts as determined by the Compensation Committee of Meira and the Company. Each grant of restricted stock shall become fully vested and owned by Employee quarterly in 1/12 increments over 3 years from the date of grant. While the Company is private, any income taxes owed by Employee from the grant of restricted stock at time of vesting shall be paid by the Company.

# C. Equity Incentives:

- i. The Company shall grant to Employee, as soon as the Compensation Committee deems reasonable but no longer than 3 (three) months after the Company has raised not less than \$70 million in debt or equity, or a combination thereof, in one or more private placements or strategic collaborations with another company (including any debt or equity already raised prior to the time of this Agreement), fully vested and owned shares representing an additional 1.50 percent of the fully diluted outstanding shares of the Company, where any income taxes owed by Employee shall be paid by the Company at time of grant. Employee agrees not to sell or transfer these shares for a period of 12 months from the date of their grant ("lock-up period").
- ii. The Company shall grant to Employee, as of the date of the earlier of (i) the date a registration statement for a class of the Company's securities become effective, or (ii) the date of a Change in Control (as defined in Section 5) of Meira or the Company, restricted stock representing an additional 2.50 percent of the fully diluted outstanding shares of the Company at the time (in the case of an IPO, the 2.50 percent shall be as of immediately after the shares are issued and offered for the IPO). 1/3 of this grant shall vest immediately and the remaining 2/3 shall vest quarterly in 1/8 increments over the next 2 years from the date of grant. The Company shall pay any income taxes owed by employee as a result of the grant at the time of vesting.

iii. The Company shall grant to Employee, as of the first day of the first payroll period after Meira or the Company becomes partially or wholly publicly owned, or becomes a subsidiary or parent of an entity that is partially or wholly publicly owned, as a result one or more strategic collaborations (including but not limited to a merger or acquisition): the equity incentives in both a. and b. of this section, where a. is: "fully vested and owned shares representing an additional 1.50 percent of the fully diluted outstanding shares of the Company, where any income taxes owed by Employee shall be paid by the Company at time of grant. Employee agrees not to sell or transfer these shares for a period of 12 months from the date of their grant ("lock-up period")"; and where b. is: "restricted stock representing an additional 2.50 percent of the fully diluted outstanding shares of the Company at the time", if sections a. and b. have not already been granted.

- D. Strategic *Collaboration Bonus*. The Company shall grant to Employee, as of the first day of the first payroll period after the Company has completed a strategic collaboration with another company, a cash bonus, if such collaboration(s) results in upfront payments of any kind, including but not limited to cash, equity, research or collaboration upfront consideration for Meira (there is no limit to the number of collaboration bonuses per annum). The cash bonus payment shall be at the discretion of the Compensation Committee provided, however, that such bonus shall not be less than 1.0% of the total upfront payments (including any cash, equity or other upfront consideration) received by Meira in any collaboration.
- E. *Incentive and Deferred Compensation*. Employee shall be eligible to participate in all incentive and deferred compensation programs available to executive officers of Meira from time to time on the same terms and conditions and extent that such programs are made available to other such executives or officers of Meira.
- F. *Employee Benefits*. Employee shall be eligible to participate in all employee benefit plans, policies, programs, or perquisites made available to employees of Meira generally or to executive officers of Meira, including any broad-based or executive stock option and stock purchase plans. The terms and conditions of Employee's participation in Meira's employee benefit plans, policies, programs, or perquisites shall be governed by the terms and conditions or practices of each such plan, policy, or program, or perquisite.
- 4. *Termination of Employment*. Employee's employment with Meira may be terminated, prior to the expiration of the term of this Agreement, in accordance with the following provision:
  - A. *Termination by Employee Without Good Reason*. The Employee may terminate Employee's employment without Good Reason (as defined in Section 4.D. of this Agreement) at any time by giving three months' notice to the Board of Meira, except that such notice is not required if the Good Reason is as defined in Section 4-D.(vi) or (vii).

Upon termination by the Employee of Employee's employment without Good Reason under this Section 4.A., Employee shall (i) be entitled to her Base Salary, Guaranteed Cash Bonuses, and Performance Cash Bonuses targeted at no less than 60% of her Base Salary as if her employment had continued for a period of an additional 12 months from

termination, (ii) be entitled to employee benefits and post-employment employee benefits and conversion rights in accordance with the terms and conditions of the plans, policies, programs, or perquisites in which she participates, (iii) be entitled to the incentive and deferred compensation incentive rights in accordance with the terms and conditions of the incentive and deferred compensation plans in which she participates, (iv) be entitled to keep any restricted stock and equity incentive awards granted under this Agreement or otherwise (including under the Performance Based Equity Incentive Agreement) that have been triggered and are vested as of the termination date, and (v) forfeit any restricted stock or equity incentive awards that are unvested on the date of termination.

B. *Termination By Death or Disability*. Employee's employment shall terminate upon the Employee's death or disability, except as prohibited by law. For purposes of this Section 4.B., disability means the inability to perform the duties of her position for a period lasting more than 180 days due to any medical condition.

Upon termination of Employee's employment upon the Employee's death or disability under this Section 4.B., Employee or her estate or beneficiary or beneficiaries shall (i) be entitled to her Base Salary, Guaranteed Cash Bonuses, and Performance Cash Bonuses targeted at no less than 60% of her Base Salary as if her employment had continued for a period of an additional 12 months from termination, (ii) be entitled to employee benefits and postemployment employee benefits and conversion rights in accordance with the terms and conditions of the plans, policies, programs, or perquisites in which she participates, (iii) be entitled to the incentive and deferred compensation incentive rights in accordance with the terms and conditions of the incentive and deferred compensation plans in which she participates, (iv) be entitled to keep any restricted stock and equity incentive awards granted under this Agreement or otherwise (including under the Performance Based Equity Incentive Agreement) that have been triggered and are vested as of the termination date, and (v) forfeit any restricted stock or equity incentive awards that are unvested on the date of termination.

C. *Termination by Meira for any reason other than Cause*. Meira may terminate Employee's employment for any reason other than Cause (as defined in Section 4.E. of this Agreement), including but not limited to termination because of a Change of Control or expiration of a term. Meira may terminate Employee's employment at any time for any reason other than Cause by giving three months' notice to the Employee. During the notice period, Employee shall remain in active employment or non-active employment as Meira may decide; provided, that Meira or the Employee may choose instead for Meira to give Employee severance pay in the amount of the remaining notice period in lieu of continued employment, to be paid within 30 days of Employee's last date of actual employment.

Upon termination by Meira of Employee's employment for any reason other than Cause under this Section 4.C., Employee shall (i) be entitled to her Base Salary, Guaranteed Cash Bonuses, and Performance Cash Bonuses targeted at no less than 60% of Base Salary as if her employment had continued for the greater of a period of 24 months from termination and such amount of time as remains until the end of the then current term under Section 2 above, including pro-rated Guaranteed Cash Bonuses and Performance Cash Bonuses targeted at 60% of Base Salary for any stub periods (for example, if Employee were

terminated for any reason other than Cause effective 7/15/17, Employee would be paid her Base Salary through 7/15/19, Employee's Guaranteed Cash Bonuses and Performance Cash Bonuses targeted at no less than 60% of Base Salary for calendar year 2017 on 1/15/18 and for calendar year 2018 on 1/15/19, and 6.5/12 of Employee's Guaranteed Cash Bonus and Performance Cash Bonus targeted at 60% of Base Salary for 2019 on 1/15/20), to be paid on the originally scheduled dates, (ii) be entitled to employee benefits and post-employment employee benefits and conversion rights in accordance with the terms and conditions of the plans, policies, programs, or perquisites in which she participates for a period of 24 months following the end of the current term (i.e., until the end of the term and then another 24 months) of the Agreement, (iii) be entitled to the incentive and deferred compensation incentive rights in accordance with the terms and conditions of the incentive and deferred compensation plans in which she participates; provided, however, that Employee shall be deemed fully vested in any incentive and deferred compensation awards under such plans upon a termination, (iv) be entitled to keep any restricted stock and equity incentive awards granted under this Agreement or otherwise that have been triggered and are vested as of the termination date, (v) be deemed upon termination fully vested in and owning any restricted stock and equity incentive awards granted under this Agreement or otherwise (including under the Performance Based Equity Incentive Agreement) that are unvested on the date of termination, (vi) be granted upon and as of the termination date fully vested and owned shares for all of the restricted stock not yet granted but provided for under Section 3-C.ii. or otherwise (including under the Performance Based Equity Incentive Agreement) as if all conditions in those sections were met, and (vii) be paid, within 30 days of termination, a cash termination fee equivalent to 1.50% of the Market Value (as defined below) of the Company shares on average during the 90-trading day period prior to the termination where any taxes owed by Employee as a result of the termination fee are to be paid by the Company ("Market Value" shall mean (a) the number computed by multiplying (i) the aggregate worldwide number of shares of the Company's voting and non-voting common equity (including stock held by employees and affiliates) by (ii) the average of the last closing prices of the Company's common equity in the principal market for such common equity; and (b) the "Market Value" shall be adjusted on a pro rata basis for any mechanical adjustments in the Company's equity resulting from forward or reverse stock splits). All of these amounts shall be paid regardless of whether Employee obtains subsequent employment.

D. *Termination by the Employee for Good Reason*. The Employee may terminate Employee's employment at any time for Good Reason. For purposes of this Section 4.D., "Good Reason" shall mean a termination of employment by the Employee for one or more of the following reasons: (i) any material diminution of the Employee's title, duties, work responsibilities, authority, or status, or the assignment of duties that would typically be performed by a Chief Executive Officer and/or President to someone other than Employee;(ii) a material negative change in Employee's reporting structure such that Employee no longer reports directly to the Board of Directors, or such that any employee or position that previously reported directly to Employee no longer reports directly to Employee; (iii) a Change in Control of Meira or the Company (as defined in Section 5); (iv) a reduction at any time in the Employee's then current Base Salary; (v) a change in Employee's principal place of employment to a location more than 15 miles from Manhattan, New York; (vi) a breach by Meira or the Company of this Agreement, which

breach is not remedied or corrected within 30 days after notice from the Employee to the Company of such breach; (vii) Meira's or the Company's insistence that Employee perform or condone any illegal conduct; or (viii) a hostile or abusive work environment or harassment (regardless of whether based on a statutorily protected characteristic such as race, age, religion, sex, sexual orientation, or the like, and regardless of whether such hostile or abusive work environment or harassment is severe or pervasive), including but not limited to verbal abuse such as the use of derogatory remarks, insults, and epithets; verbal, non-verbal, or physical conduct of a threatening, intimidating, or humiliating nature; the sabotage or undermining of Employee's work performance; bullying; or retaliation for a good faith complaint that a hostile or abusive work environment or harassment exists.

Upon termination by the Employee's employment for Good Reason under this Section 4.D., Employee shall be entitled to the same rights and payments as if Employee's employment had been terminated by Meira for any reason other than Cause pursuant to Section 4.C. of this Agreement.

E. *Termination by Meira For Cause*. Meira may terminate Employee's employment hereunder for Cause. For purposes of this Section 4.E., Cause means (a) conviction of a felony involving moral turpitude; (b) embezzlement; or (c) intentional and willful misconduct that may subject Meira to criminal liability, which misconduct is not remedied, corrected, and/or cured within 30 days after written notice from Meira to Employee of such breach, if remediable, correctable, or curable.

Upon termination by Meira of Employee's employment for Cause under this Section 4.E., Employee shall (i) be entitled to her Base Salary through the date of termination, (ii) be entitled to employee benefits and post-employment employee benefits and conversion rights in accordance with the terms and conditions of the plans, policies, programs, or perquisites in which she participates, (iii) be entitled to the incentive and deferred compensation Incentive rights in accordance with the terms and conditions of the incentive and deferred compensation plans in which she participates, (iv) be entitled to keep any restricted stock or equity incentive awards granted under this Agreement or otherwise (including under the Performance Based Equity Incentive Agreement) that have been triggered and are vested as of the termination date, and (v) forfeit any restricted stock or equity incentive awards that are unvested on the date of termination.

- 5. Change of Control. For purposes of this Agreement, "Change in Control" shall mean: (i) the sale or other disposition of all or substantially all of the assets of Meira or the Company; (ii) any sale or exchange of the capital stock of the Company by the stockholders of the Company in one transaction or series of related transactions where more than fifty percent (50%) of the outstanding voting power of the Company is acquired by a person or entity or group of related persons or entities; (iii) any reorganization, consolidation or merger of the Company where the outstanding voting securities of the Company immediately before the transaction represent or are converted into less than fifty percent (50%) of the outstanding voting power of the surviving entity (or its parent corporation) immediately after the transaction; or (iv) the consummation of the acquisition of fifty-one percent (51%) or more of the outstanding stock of the Company pursuant to a tender offer validly made under any federal or state law (other than a tender offer by the Company).
- 6. Confidentiality. Employee agrees that at all times during Employee's employment and following the conclusion of Employee's employment hereunder, whether voluntary or involuntary, Employee will hold in strictest confidence and not disclose Confidential Information (as defined below) to anyone who is not also an employee of Meira or the Company or to any employee of Meira or the Company who does not also have access to such Confidential Information, other than to an attorney to obtain legal advice, without express written authorization of the Board of Meira. For purposes of this Section 6, Confidential Information means any trade secrets or Company proprietary information, including but not limited to manufacturing techniques, processes, formulas, inventions, experimental developments, research projects, operating methods, cost, pricing, financial data, business plans and proposals, data and information Meira or the Company receives in confidence from any other party, or any other secret or confidential matters of the Company. Additionally, Employee will not use any Confidential Information for Employee's own benefit or to the detriment of Meira or the Company during Employee's employment or thereafter. Employee also certifies that employment with Meira does not and will not breach any agreement or duty that Employee has to anyone concerning confidential information belonging to others.
- 7. *Expenses*. Meira shall pay or reimburse Employee for any expenses reasonably incurred by Employee in furtherance of Employee's duties hereunder, including expenses for entertainment, travel, meals and hotel accommodations, upon submission by Employee of expense reports in accordance with such rules and policies relating thereto as Meira may from time to time adopt.

#### 8. General Provisions.

A. *Notices*. All notices and other communications required or permitted by this Agreement to be delivered to Meira or the Company or Employee to the other party shall be delivered in writing to the address shown below, either personally, by electronic mail, by facsimile transmission, or by registered, certified, or express mail, return receipt requested, postage prepaid, to the address for such party specified below or to such other address as the party may from time to time advise the other party in writing in the same manner as set forth in this Section 8.A., and shall be deemed given and received as of actual personal delivery, on the first business day after the date of delivery shown on any such electronic mail or facsimile transmission or upon the date or actual receipt shown on any return receipt if registered, certified, or express mail is used, as the case may be.

## Company:

MeiraCTx 450 East 29th Street, 15th Floor New York, NY 10016 Attention: Rich Giroux, COO rich@meiragtx.com

#### Employee:

Alexandria Forbes 14 East 10<sup>th</sup> Street, #2 New York, NY 10003 <u>zandy@meiragtx.com</u> 917-400-5590

- B. Amendments and Termination; Entire Agreement. This Agreement may not be amended or terminated except by a writing executed by all of the parties hereto. This Agreement, along with the Performance Based Equity Incentive Agreement between the Company and Meira and Employee, constitutes the entire agreement of the Company and Meira and Employee relating to the subject matter hereof and supersedes all prior oral and written understandings and agreements relating to such subject matter.
- C. *Successors and Assigns*. The rights and obligations of the parties hereunder are not assignable to another person without prior written consent; provided, however, that Meira's and the Company's obligations hereunder shall be binding upon their successors and assigns.
- D. Severability; Provisions Subject to Applicable Law. All provisions of this Agreement shall be applicable only to the extent that they do not violate any applicable law, and are intended to be limited to the extent necessary so that they will not render this Agreement invalid, illegal or unenforceable under any applicable law. If any provision of this Agreement or any application thereof shall be held to be invalid, illegal or unenforceable, the validity, legality and enforceability of other provisions of this Agreement or of any other application of such provision shall in no way be affected thereby.
- E. *Waiver of Rights*. No waiver by Meira, the Company or Employee of a right or remedy hereunder shall be deemed to be a waiver of any other right or remedy or of any subsequent right or remedy of the same kind.
- F. *Definitions; Headings; Number.* A term defined in any part of this Agreement shall have the defined meaning wherever such term is used herein. The headings contained in this Agreement are for reference purposes only and shall not affect in any manner the meaning or interpretation of this Agreement. Where appropriate to the context of this Agreement, use of the singular shall be deemed also to refer to the plural, and use of the plural to the singular.

- G. Counterparts. This Agreement may be executed in separate counterparts and by facsimile, electronic, or pdf, each of which shall be deemed an original but both of which taken together shall constitute but one and the same instrument.
- H. *Governing Laws; Forum; Legal Fees.* This Agreement shall be governed by, construed, and enforced in accordance with the laws of the State of New York. The parties hereto further agree that any action brought to enforce any right or obligation under this Agreement shall be subject to the exclusive jurisdiction of the state or federal courts of the State of New York. If Employee brings suit against Meira and/or the Company arising from or related to this Agreement, Meira and the Company shall pay Employee's attorneys' fees and costs incurred in such suit on a monthly basis.

IN WITNESS WHEREOF, Meira, the Company and Employee have executed and delivered this Agreement as of the date first written above.

#### **MEIRAGTX**

/s/ Tom Shenk Date: February 24rd, 2016

Tom Shenk

Chairman of the Board, MeiraGTx

/s/ Keith Harris Date: February 24th, 2016

Keith Harris

Chairman, Compensation Committee, MeiraGTx

## ALEXANDRIA FORBES

/s/ Alexandria Forbes Date: February 24th, 2016

Alexandria Forbes

# EXHIBIT 1

The following outside business interests are disclosed pursuant to Section 1 of this Agreement:

#### EMPLOYMENT AGREEMENT AMENDMENT

This Employment Agreement Amendment (the "<u>Amendment</u>") is made as of May 28, 2018 (the "<u>Amendment Date</u>") by and among MeiraGTx Limited and MeiraGTx LLC (together, the "<u>Company</u>") and Alexandria Forbes (the "<u>Employee</u>"). Except as set forth in this Amendment, capitalized terms used but not defined herein shall have the meanings ascribed to them in the Employment Agreement (as defined below).

#### WITNESSETH

WHEREAS, Employee previously entered into an employment agreement with the Company effective as of February 15, 2016 (the "Employment Agreement"); and

WHEREAS, the Employee and the Company each desire to amend the terms of the Employment Agreement as set forth in this Amendment.

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Employee and the Company hereby agree to the following:

- Amendment to the Employment Agreement. Effective as of the Amendment Date, the Employment Agreement is hereby amended by adding a new Section 8.I as follows:
  - I. Section 409A.
  - i. The intent of the parties is that the payments and benefits under this Agreement comply with or be exempt from Section 409A ("Section 409A") of the Internal Revenue Code of 1986, as amended, and the regulations and guidance promulgated thereunder (the "Code") and, accordingly, to the maximum extent permitted, this Agreement shall be interpreted to be in compliance therewith.
  - ii. Notwithstanding anything in this Agreement to the contrary, any compensation or benefits payable under this Agreement that is designated under this Agreement as payable upon Employee's termination of employment shall be payable only upon Employee's "separation from service" with the Company within the meaning of Section 409A (a "Separation from Service").
  - iii. Notwithstanding anything in this Agreement to the contrary, if Employee is deemed by the Company at the time of Employee's Separation from Service to be a "specified employee" for purposes of Section 409A, to the extent delayed commencement of any portion of the benefits to which Employee is entitled under this Agreement is required in order to avoid a prohibited distribution under Section 409A, such portion of Employee's benefits shall not be provided to Employee prior to the earlier of (i) the expiration of the six-month period measured from the date of Employee's Separation from Service with the Company or (ii) the date of Employee's death. Upon the first business day following the expiration of the applicable Section 409A period, all payments deferred pursuant to the preceding sentence shall be paid in a lump sum to Employee (or Employee's estate or beneficiaries), and any remaining payments due to Employee under this Agreement shall be paid as otherwise provided herein.

- iv. To the extent that any reimbursements under this Agreement are subject to Section 409A, any such reimbursements payable to Employee shall be paid to Employee no later than December 31 of the year following the year in which the expense was incurred; provided, that Employee submits Employee's reimbursement request promptly following the date the expense is incurred, the amount of expenses reimbursed in one year shall not affect the amount eligible for reimbursement in any subsequent year, other than medical expenses referred to in Section 105(b) of the Code, and Employee's right to reimbursement under this Agreement will not be subject to liquidation or exchange for another benefit.
- v. Except as otherwise permitted under Section 409A, no payment hereunder shall be accelerated or deferred unless such acceleration or deferral would not result in additional tax or interest pursuant to Section 409A.
- 2. <u>No Other Amendment</u>. Except as expressly set forth in this Amendment, the Employment Agreement shall remain unchanged and shall continue in full force and effect according to its terms.
- 3. <u>Entire Agreement</u>. This Amendment, together with the Employment Agreement (to the extent not amended hereby), represents the entire agreement of the parties with respect to the subject matter hereof and shall supersede any and all previous contracts, arrangements or understandings between the parties.

[signature page follows]

IN WITNESS WHEREOF, the Company and the Employee have executed this Amendment as of the date first written above.

## MEIRAGTX LIMITED

By: /s/ Richard Giroux
Name: Richard Giroux

Title: Officer

## MEIRAGTX LLC

By: /s/ Richard Giroux

Name: Richard Giroux

Title: Chief Operating Officer

## **EMPLOYEE**

/s/ Alexandria Forbes, Ph.D.

Alexandria Forbes, Ph.D.

#### **Employment Agreement**

This Employment Agreement ("Agreement") is entered into effective as of February 15<sup>th</sup>, 2016, by and between MeiraGTx LLC ("Meira"), a Delaware limited liability company, and its parent MeiraGTx Limited and subsidiaries (together, the "Company" or "MeiraGTx"), and Richard Giroux ("Employee").

In consideration of the mutual promises and covenants set forth herein, and other good and valuable consideration, the sufficiency of which is hereby acknowledged, the Company and Employee hereby agree as follows:

- 1. *Position of Employment*. Meira will employ the Employee in the position of Chief Operating Officer and Head of Corporate Development of Meira and, in that position, Employee will report directly to the Chief Executive Officer of Meira. In the event of a conflict between this Agreement and any Company policies, procedures, and practices, the terms of this Agreement shall govern. Except as disclosed on Exhibit 1, Employee shall not undertake, either as an owner, director, shareholder, employee, or otherwise, the performance of services for compensation (actual or expected) for any other entity without the express written consent of the Chief Executive Officer ("CEO") of Meira.
- 2. *Term of Employment*. Employee's employment with Meira shall begin on February 15th, 2016, and shall continue until February 15th, 2019. Unless Employee or Meira gives notice of non-renewal to the other party at least 90 days before the expiration of the 3-year initial term (or each 1- year successive term), this Agreement and Employee's employment shall be *automatically renewed* and extended for additional 1-year periods. During a term, Employee's employment may be terminated only in accordance with Section 4 of this Agreement.
- 3. Compensation and Benefits.

A. Base Salary. Employee shall initially be paid a base salary of \$320,000 in cash annually by Meira, to be paid in accordance with Meira's regular payroll policies but no less frequently than twice per month ("Base Salary"). Employee's Base Salary shall be increased to \$400,000 in cash annually as of the first payroll period following when the Company raises a total of \$25 million in debt or equity, or a combination thereof, in one or more private placements (including any debt or equity already raised prior to the time of this Agreement). Employee's Base Salary shall be increased to \$495,000 in cash annually as of the first day of the first payroll period following the earlier of (i) the date a registration statement for a class of the Company's securities becomes effective; or (ii) the date of a Change in Control of Meira or the Company (as defined in Section 5); or (iii) the date when the Company raises a total of \$75 million in debt or equity, in one or more private placements or strategic collaborations or corporate partnerships with another company (including any debt or equity already raised prior to the time of this Agreement). In addition, Employee's Base Salary shall be reviewed annually or periodically in accordance with Meira's normal compensation review cycle, but any increase above the amounts herein specified shall be in the sole discretion of Meira management, and nothing herein shall be deemed to require any such increase other than as set forth above; provided, however, that Employee's Base Salary shall not be reduced.

#### B. Bonuses.

- i. *Annual Bonus*. Employee's Annual Guaranteed Cash Bonus from Meira shall be 100% of Employee's Base Salary in effect at the time of payment. It shall be paid by January 15 of the following year.
- ii. *Performance Bonus*. Employee's Annual Performance Cash Bonus from Meira shall be determined by the CEO of Meira and shall be targeted at no less than 50% of salary. It shall be paid by January 15 of the following year. (For the avoidance of doubt, the Annual Performance Cash Bonus is in addition to the Annual Guaranteed Cash bonus.)
- iii. *Annual Performance Grants of Restricted Stock*. Employee shall be granted restricted stock for each year by January 15 of the following year, in amounts as determined by the CEO of Meira and the Company. Each grant of restricted stock shall become fully vested and owned by Employee quarterly in 1/12 increments over 3 years from the date of grant. While the Company is private, any income taxes owed by Employee from the grant of restricted stock at time of vesting shall be paid by the Company.

#### C. Equity Incentives:

- i. The Company shall grant to Employee, as soon as the Compensation Committee deems reasonable but no longer than 3 (three) months after the Company has raised not less than \$70 million in debt or equity, or a combination thereof, in one or more private placements or strategic collaborations with another company (including any debt or equity already raised prior to the time of this Agreement), fully vested and owned shares representing an additional 1.50 percent of the fully diluted outstanding shares of the Company, where any income taxes owed by Employee shall be paid by the Company at time of grant. Employee agrees not to sell or transfer these shares for a period of 12 months from the date of their grant ("lock-up period").
- ii. The Company shall grant to Employee, as of the date of the earlier of (i) the date a registration statement for a class of the Company's securities become effective, or (ii) the date of a Change in Control (as defined in Section 5) of Meira or the Company, restricted stock representing an additional 2.50 percent of the fully diluted outstanding shares of the Company at the time (in the case of an IPO, the 2.00 percent shall be as of immediately after the shares are issued and offered for the IPO). 1/3 of this grant shall vest immediately and the remaining 2/3 shall vest quarterly in 1/8 increments over the next 2 years from the date of grant. The Company shall pay any income taxes owed by employee as a result of the grant at the time of vesting.

iii. The Company shall grant to Employee, as of the first day of the first payroll period after Meira or the Company becomes partially or wholly publicly owned, or becomes a subsidiary or parent of an entity that is partially or wholly publicly owned, as a result one or more strategic collaborations (including but not limited to a merger or acquisition): the equity incentives in both a. and b. of this section, where a. is: "fully vested and owned shares representing an additional 1.50 percent of the fully diluted outstanding shares of the Company, where any income taxes owed by Employee shall be paid by the Company at time of grant. Employee agrees not to sell or transfer these shares for a period of 12 months from the date of their grant ("lock-up period")"; and where b. is: "restricted stock representing an additional 2.50 percent of the fully diluted outstanding shares of the Company at the time", if sections a. and b. have not already been granted.

- D. Strategic Collaboration Bonus. The Company shall grant to Employee, as of the first day of the first payroll period after the Company has completed a strategic collaboration with another company, a cash bonus, if such collaboration(s) results in upfront payments of any kind, including but not limited to cash, equity, research or collaboration upfront consideration for Meira (there is no limit to the number of collaboration bonuses per annum). The cash bonus payment shall be at the discretion of the CEO and Compensation Committee provided, however, that such bonus shall not be less than 1.0% of the total upfront payments (including any cash, equity or other upfront consideration) received by Meira in any collaboration.
- E. *Incentive and Deferred Compensation*. Employee shall be eligible to participate in all incentive and deferred compensation programs available to executive officers of Meira from time to time on the same terms and conditions and extent that such programs are made available to other such executives or officers of Meira.
- F. *Employee Benefits*. Employee shall be eligible to participate in all employee benefit plans, policies, programs, or perquisites made available to employees of Meira generally or to executive officers of Meira, including any broad-based or executive stock option and stock purchase plans. The terms and conditions of Employee's participation in Meira's employee benefit plans, policies, programs, or perquisites shall be governed by the terms and conditions or practices of each such plan, policy, or program, or perquisite.
- 4. *Termination of Employment*. Employee's employment with Meira may be terminated, prior to the expiration of the term of this Agreement, in accordance with the following provision:
  - A. *Termination by Employee Without Good Reason*. The Employee may terminate Employee's employment without Good Reason (as defined in Section 4.D. of this Agreement) at any time by giving three months' notice to the CEO of Meira, except that such notice is not required if the Good Reason is as defined in Section 4.D.(vi) or (vii).

Upon termination by the Employee of Employee's employment without Good Reason under this Section 4.A., Employee shall (i) be entitled to his Base Salary, Guaranteed Cash Bonuses, and Performance Cash Bonuses targeted at no less than 50% of his Base Salary as if his employment had continued for a period of an additional 12 months from termination, (ii) be entitled to employee benefits and post-employment employee benefits and conversion rights in accordance with the terms and conditions of the plans, policies, programs, or perquisites in which he participates, (iii) be entitled to the incentive and

deferred compensation incentive rights in accordance with the terms and conditions of the incentive and deferred compensation plans in which he participates, (iv) be entitled to keep any restricted stock and equity incentive awards granted under this Agreement or otherwise (including under the Performance Based Equity Incentive Agreement) that have been triggered and are vested as of the termination date, and (v) forfeit any restricted stock or equity incentive awards that are unvested on the date of termination.

B. *Termination By Death or Disability*. Employee's employment shall terminate upon the Employee's death or disability, except as prohibited by law. For purposes of this Section 4.B., disability means the inability to perform the duties of his position for a period lasting more than 180 days due to any medical condition.

Upon termination of Employee's employment upon the Employee's death or disability under this Section 4.B., Employee or his estate or beneficiary or beneficiaries shall (i) be entitled to his Base Salary, Guaranteed Cash Bonuses, and Performance Cash Bonuses targeted at no less than 50% of his Base Salary as if his employment had continued for a period of an additional 12 months from termination, (ii) be entitled to employee benefits and postemployment employee benefits and conversion rights in accordance with the terms and conditions of the plans, policies, programs, or perquisites in which he participates, (iii) be entitled to the incentive and deferred compensation incentive rights in accordance with the terms and conditions of the incentive and deferred compensation plans in which he participates, (iv) be entitled to keep any restricted stock and equity incentive awards granted under this Agreement or otherwise (including under the Performance Based Equity Incentive Agreement) that have been triggered and are vested as of the termination date, and (v) forfeit any restricted stock or equity incentive awards that are unvested on the date of termination.

C. *Termination by Meira for any reason other than Cause*. Meira may terminate Employee's employment for any reason other than Cause (as defined in Section 4.E. of this Agreement), including but not limited to termination because of a Change of Control or expiration of a term. Meira may terminate Employee's employment at any time for any reason other than Cause by giving three months' notice to the Employee. During the notice period, Employee shall remain in active employment or non-active employment as Meira may decide; provided, that Meira or the Employee may choose instead for Meira to give Employee severance pay in the amount of the remaining notice period in lieu of continued employment, to be paid within 30 days of Employee's last date of actual employment.

Upon termination by Meira of Employee's employment for any reason other than Cause under this Section 4.C., Employee shall (i) be entitled to his Base Salary, Guaranteed Cash Bonuses, and Performance Cash Bonuses targeted at no less than 50% of Base Salary as if his employment had continued for the greater of a period of 24 months from termination and such amount of time as remains until the end of the then current term under Section 2 above, including pro-rated Guaranteed Cash Bonuses and Performance Cash Bonuses targeted at 50% of Base Salary for any stub periods (for example, if Employee were terminated for any reason other than Cause effective 7/15/17, Employee would be paid his Base Salary through 7/15/19, Employee's Guaranteed Cash Bonuses and Performance Cash Bonuses targeted at 50% of Base Salary for calendar year 2017 on 1/15/18 and for

calendar year 2018 on 1/15/19, and 6.5/12 of Employee's Guaranteed Cash Bonus and Performance Cash Bonus targeted at no less than 50% of Base Salary for 2019 on 1/15/20), to be paid on the originally scheduled dates, (ii) be entitled to employee benefits and post-employment employee benefits and conversion rights in accordance with the terms and conditions of the plans, policies, programs, or perquisites in which he participates for a period of 24 months following the end of the current term (i.e., until the end of the term and then another 24 months) of the Agreement, (iii) be entitled to the incentive and deferred compensation incentive rights in accordance with the terms and conditions of the incentive and deferred compensation plans in which he participates; provided, however, that Employees shall be deemed fully vested in any incentive and deferred compensation awards under such plans upon a termination, (iv) be entitled to keep any restricted stock and equity incentive awards granted under this Agreement or otherwise that have been triggered and are vested as of the termination date, (v) be deemed upon termination fully vested in and owning any restricted stock and equity incentive awards granted under this Agreement or otherwise (including under the Performance Based Equity Incentive Agreement) that are unvested on the date of termination, (vi) be granted upon and as of the termination date fully vested and owned shares for all of the restricted stock not yet granted but provided for under Section 3-C.ii. or otherwise (including under the Performance Based Equity Incentive Agreement) as if all conditions in those sections were met, and (vii) be paid, within 30 days of termination, a cash termination fee equivalent to 1.00% of the Market Value (as defined below) of the Company shares on average during the 90-trading day period prior to the termination where any taxes owed by Employee as a result of the termination fee are to be paid by the Company ("Market Value" shall mean (a) the number computed by multiplying (i) the aggregate worldwide number of shares of the Company's voting and non-voting common equity (including stock held by employees and affiliates) by (ii) the average of the last closing prices of the Company's common equity in the principal market for such common equity; and (b) the "Market Value" shall be adjusted on a pro rata basis for any mechanical adjustments in the Company's equity resulting from forward or reverse stock splits), All of these amounts shall be paid regardless of whether Employee obtains subsequent employment.

D. Termination by the Employee for Good Reason. The Employee may terminate Employee's employment at any time for Good Reason. For purposes of this Section 4.D., "Good Reason" shall mean a termination of employment by the Employee for one or more of the following reasons: (i) any material diminution of the Employees' title, duties, work responsibilities, authority, or status, or the assignment of duties that would typically be performed by a Chief Operating Officer and/or Head of Corporate Development to someone other than Employee; (ii) a material negative change in Employee's reporting structure such that Employee no longer reports directly to the CEO, or such that any employee or position that previously reported directly to Employee no longer reports directly to Employee; (iii) a Change in Control of Meira or the Company (as defined in Section 5); (iv) a reduction at any time in the Employee's then current Base Salary; (v) a change in Employee's principal place of employment to a location more than 15 miles from Manhattan, New York; (vi) a breach by Meira or the Company of this Agreement, which breach is not remedied or corrected within 30 days after notice from the Employee to the Company of such breach; (vii) Meira's or the Company's insistence that Employee perform or condone any illegal conduct; or (viii) a hostile or abusive work environment or

harassment (regardless of whether based on a statutorily protected characteristic such as race, age, religion, sex, sexual orientation, or the like, and regardless of whether such hostile or abusive work environment or harassment is severe or pervasive), including but not limited to verbal abuse such as the use of derogatory remarks, insults, and epithets; verbal, non-verbal, or physical conduct of a threatening, intimidating, or humiliating nature; the sabotage or undermining of Employee's work performance; bullying; or retaliation for a good faith complaint that a hostile or abusive work environment or harassment exists.

Upon termination by the Employee's employment for Good Reason under this Section 4.D., Employee shall be entitled to the same rights and payments as if Employee's employment had been terminated by Meira for any reason other than Cause pursuant to Section 4.C. of this Agreement.

E. *Termination by Meira For Cause*. Meira may terminate Employee's employment hereunder for Cause. For purposes of this Section 4.E., Cause means (a) conviction of a felony involving moral turpitude; (b) embezzlement; or (c) intentional and willful misconduct that may subject Meira to criminal liability, which misconduct is not remedied, corrected, and/or cured within 30 days after written notice from Meira to Employee of such breach, if remediable, correctable, or curable.

Upon termination by Meira of Employee's employment for Cause under this Section 4.E., Employee shall (i) be entitled to his Base Salary through the date of termination, (ii) be entitled to employee benefits and post-employment employee benefits and conversion rights in accordance with the terms and conditions of the plans, policies, programs, or perquisites in which he participates, (iii) be entitled to the incentive and deferred compensation Incentive rights in accordance with the terms and conditions of the incentive and deferred compensation plans in which he participates, (iv) be entitled to keep any restricted stock or equity incentive awards granted under this Agreement or otherwise (including under the Performance Based Equity Incentive Agreement) that have been triggered and are vested as of the termination date, and (v) forfeit any restricted stock or equity incentive awards that are unvested on the date of termination.

5. Change of Control. For purposes of this Agreement, "Change in Control" shall mean: (i) the sale or other disposition of all or substantially all of the assets of Meira or the Company; (ii) any sale or exchange of the capital stock of the Company by the stockholders of the Company in one transaction or series of related transactions where more than fifty percent (50%) of the outstanding voting power of the Company is acquired by a person or entity or group of related persons or entities; (iii) any reorganization, consolidation or merger of the Company where the outstanding voting securities of the Company immediately before the transaction represent or are converted into less than fifty percent (50%) of the outstanding voting power of the surviving entity (or its parent corporation) immediately after the transaction; or (iv) the consummation of the acquisition of fifty- one percent (51%) or more of the outstanding stock of the Company pursuant to a tender offer validly made under any federal or state law (other than a tender offer by the Company).

- 6. Confidentiality. Employee agrees that at all times during Employee's employment and following the conclusion of Employee's employment hereunder, whether voluntary or involuntary, Employee will hold in strictest confidence and not disclose Confidential Information (as defined below) to anyone who is not also an employee of Meira or the Company or to any employee of Meira or the Company who does not also have access to such Confidential Information, other than to an attorney to obtain legal advice, without express written authorization of the CEO of Meira. For purposes of this Section 6, Confidential Information means any trade secrets or Company proprietary information, including but not limited to manufacturing techniques, processes, formulas, inventions, experimental developments, research projects, operating methods, cost, pricing, financial data, business plans and proposals, data and information Meira or the Company receives in confidence from any other party, or any other secret or confidential matters of the Company. Additionally, Employee will not use any Confidential Information for Employee's own benefit or to the detriment of Meira or the Company during Employee's employment or thereafter. Employee also certifies that employment with Meira does not and will not breach any agreement or duty that Employee has to anyone concerning confidential information belonging to others.
- 7. *Expenses*. Meira shall pay or reimburse Employee for any expenses reasonably incurred by Employee in furtherance of Employee's duties hereunder, including expenses for entertainment, travel, meals and hotel accommodations, upon submission by Employee of expense reports in accordance with such rules and policies relating thereto as Meira may from time to time adopt.

#### 8. General Provisions.

A. *Notices*. All notices and other communications required or permitted by this Agreement to be delivered to Meira or the Company or Employee to the other party shall be delivered in writing to the address shown below, either personally, by electronic mail, by facsimile transmission, or by registered, certified, or express mail, return receipt requested, postage prepaid, to the address for such party specified below or to such other address as the party may from time to time advise the other party in writing in the same manner as set forth in this Section 8.A., and shall be deemed given and received as of actual personal delivery, on the first business day after the date of delivery shown on any such electronic mail or facsimile transmission or upon the date or actual receipt shown on any return receipt if registered, certified, or express mail is used, as the case may be.

### Company:

Alexandria Forbes, CEO MeiraGTx 450 East 29th Street, 15th Floor New York, NY 10016 zandy@meiragtx.com

#### Employee:

Richard Giroux 69 Perry Street, #5 New York, NY, 10014 rich@meiragtx.com 646-932-0208

- B. Amendments and Termination; Entire Agreement. This Agreement may not be amended or terminated except by a writing executed by all of the parties hereto. This Agreement, along with the Performance Based Equity Incentive Agreement between the Company and Meira and Employee, constitutes the entire agreement of the Company and Meira and Employee relating to the subject matter hereof and supersedes all prior oral and written understandings and agreements relating to such subject matter.
- C. Successors and Assigns. The rights and obligations of the parties hereunder are not assignable to another person without prior written consent; provided, however, that Meira's and the Company's obligations hereunder shall be binding upon their successors and assigns.
- D. Severability; Provisions Subject to Applicable Law. All provisions of this Agreement shall be applicable only to the extent that they do not violate any applicable law, and are intended to be limited to the extent necessary so that they will not render this Agreement invalid, illegal or unenforceable under any applicable law. If any provision of this Agreement or any application thereof shall be held to be invalid, illegal or unenforceable, the validity, legality and enforceability of other provisions of this Agreement or of any other application of such provision shall in no way be affected thereby.
- E. *Waiver of Rights*. No waiver by Meira, the Company or Employee of a right or remedy hereunder shall be deemed to be a waiver of any other right or remedy or of any subsequent right or remedy of the same kind.
- F. *Definitions; Headings; Number.* A term defined in any part of this Agreement shall have the defined meaning wherever such term is used herein. The headings contained in this Agreement are for reference purposes only and shall not affect in any manner the meaning or interpretation of this Agreement. Where appropriate to the context of this Agreement, use of the singular shall be deemed also to refer to the plural, and use of the plural to the singular.
- G. *Counterparts*. This Agreement may be executed in separate counterparts and by facsimile, electronic, or pdf, each of which shall be deemed an original but both of which taken together shall constitute but one and the same instrument.
- H. *Governing Laws; Forum; Legal Fees.* This Agreement shall be governed by, construed, and enforced in accordance with the laws of the State of New York. The parties hereto further agree that any action brought to enforce any right or obligation under this Agreement shall be subject to the exclusive jurisdiction of the state or federal courts of the State of New York. If Employee brings suit against Meira and/or the Company arising from or related to this Agreement, Meira and the Company shall pay Employee's attorneys' fees and costs incurred in such suit on a monthly basis.

IN WITNESS WHEREOF, Meira, the Company and Employee have executed and delivered this Agreement as of the date first written above.

MEIRAGTX

/s/ Alexandria Forbes Date: February 24th, 2016

Alexandria Forbes CEO, MeiraGTx

MEIRAGTX

/s/ Tom Shenk Date: February 23rd, 2016

Tom Shenk

Chairman of the Board, MeiraGTx

/s/ Keith Harris Date: February 24th, 2016

Keith Harris

Chairman, Compensation Committee, MeiraGTx

RICHARD GIROUX

/s/ Richard Giroux Date: February 17th, 2016

Richard Giroux

## **EXHIBIT 1**

The following outside business interests are disclosed pursuant to Section 1 of this Agreement:

- Aigle HC Partners I, LLC
   Aigle HC Partners II, LLC
   Perry Consultants, LLC

#### EMPLOYMENT AGREEMENT AMENDMENT

This Employment Agreement Amendment (the "<u>Amendment</u>") is made as of May 28, 2018 (the "<u>Amendment Date</u>") by and among MeiraGTx Limited and MeiraGTx LLC (together, the "<u>Company</u>") and Richard Giroux (the "<u>Employee</u>"). Except as set forth in this Amendment, capitalized terms used but not defined herein shall have the meanings ascribed to them in the Employment Agreement (as defined below).

#### WITNESSETH

WHEREAS, Employee previously entered into an employment agreement with the Company effective as of February 15, 2016 (the "Employment Agreement"); and

WHEREAS, the Employee and the Company each desire to amend the terms of the Employment Agreement as set forth in this Amendment.

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Employee and the Company hereby agree to the following:

- 1. <u>Amendment to the Employment Agreement</u>. Effective as of the Amendment Date, the Employment Agreement is hereby amended by adding a new Section 8.I as follows:
  - I. Section 409A.
  - i. The intent of the parties is that the payments and benefits under this Agreement comply with or be exempt from Section 409A ("Section 409A") of the Internal Revenue Code of 1986, as amended, and the regulations and guidance promulgated thereunder (the "Code") and, accordingly, to the maximum extent permitted, this Agreement shall be interpreted to be in compliance therewith.
  - ii. Notwithstanding anything in this Agreement to the contrary, any compensation or benefits payable under this Agreement that is designated under this Agreement as payable upon Employee's termination of employment shall be payable only upon Employee's "separation from service" with the Company within the meaning of Section 409A (a "Separation from Service").
  - iii. Notwithstanding anything in this Agreement to the contrary, if Employee is deemed by the Company at the time of Employee's Separation from Service to be a "specified employee" for purposes of Section 409A, to the extent delayed commencement of any portion of the benefits to which Employee is entitled under this Agreement is required in order to avoid a prohibited distribution under Section 409A, such portion of Employee's benefits shall not be provided to Employee prior to the earlier of (i) the expiration of the six-month period measured from the date of Employee's Separation from Service with the Company or (ii) the date of Employee's death. Upon the first business day following the expiration of the applicable Section 409A period, all payments deferred pursuant to the preceding sentence shall be paid in a lump sum to Employee (or Employee's estate or beneficiaries), and any remaining payments due to Employee under this Agreement shall be paid as otherwise provided herein.

- iv. To the extent that any reimbursements under this Agreement are subject to Section 409A, any such reimbursements payable to Employee shall be paid to Employee no later than December 31 of the year following the year in which the expense was incurred; provided, that Employee submits Employee's reimbursement request promptly following the date the expense is incurred, the amount of expenses reimbursed in one year shall not affect the amount eligible for reimbursement in any subsequent year, other than medical expenses referred to in Section 105(b) of the Code, and Employee's right to reimbursement under this Agreement will not be subject to liquidation or exchange for another benefit.
- v. Except as otherwise permitted under Section 409A, no payment hereunder shall be accelerated or deferred unless such acceleration or deferral would not result in additional tax or interest pursuant to Section 409A.
- 2. <u>No Other Amendment</u>. Except as expressly set forth in this Amendment, the Employment Agreement shall remain unchanged and shall continue in full force and effect according to its terms.
- 3. <u>Entire Agreement</u>. This Amendment, together with the Employment Agreement (to the extent not amended hereby), represents the entire agreement of the parties with respect to the subject matter hereof and shall supersede any and all previous contracts, arrangements or understandings between the parties.

[signature page follows]

IN WITNESS WHEREOF, the Company and the Employee have executed this Amendment as of the date first written above.

## MEIRAGTX LIMITED

By: /s/ Alexandria Forbes
Name: Alexandria Forbes
Title: CEO MEIRAGTX

## MEIRAGTX LLC

By: /s/ Alexandria Forbes

Name: Alexandria Forbes

Title: CEO MEIRAGTX

## **EMPLOYEE**

/s/ Richard Giroux

Richard Giroux

#### **Service Agreement**

this agreement made the 27th day of April 2015

#### **BETWEEN:**

- (1) Athena Vision Limited (registered number 09348737) whose registered office is at C/O UCL Business PLC The Network Building 97 Tottenham Court Road, London W1T 4TP (the "Company") and
- (2) Stuart Naylor of 40 Longfield Drive, Amersham, Buckinghamshire HP6 5HE (the "Executive").

#### WHEREAS:

The Company wishes to employ the Executive and the Executive has agreed to serve the Company as Chief Executive Officer on the terms and conditions set out in this Agreement.

## IT IS AGREED:

#### 1. APPOINTMENT AND TERM

The Company shall employ the Executive and the Executive shall serve the Company as Chief Executive Officer with a further role as Chief Development Officer with effect from April 27th, 2015. Either the Executive or the Company may terminate the employment at any time by giving to the other not less than 12 months' notice in writing.

## 2. DUTIES

- 2.1 During his employment hereunder the Executive shall:
  - (a)
- (i) perform functions consistent with his role as Chief Executive Officer and perform such other duties and exercise the powers and functions which from time to time may reasonably be assigned to or vested in him by the Board of Directors of the Company (the "Board") in relation to the Company and any Associated Company (as defined in clause 16 below) at such place or places both within and outside the United Kingdom as the Board shall determine;
- (ii) (in his capacity as Chief Development Officer, research, develop and conceive of ways of using gene therapy in the diagnosis, treatment, management and/or prevention of conditions and diseases in humans and animals,

(together the "Development Duties");

- (b) during working hours devote the whole of his time, attention and ability to the Development Duties and shall faithfully and loyally serve the Company to the best of his ability and use his utmost endeavours to promote its interests in all respects;
- (c) comply with all reasonable requests, instructions and regulations given or made by the Board (or by any one authorised by it) in relation to the Development Duties and promptly provide such explanations, information and assistance as to his activities or the business of the Company as the Board may reasonably require; and
- (d) not engage in any activities which would detract from the proper performance of his duties hereunder, nor without the prior written consent of the Board in any capacity including as director, shareholder, principal, consultant, agent, partner or employee of any other company, firm or person (save as the holder for investment of securities which do not exceed three per cent (3%) in nominal value of the share capital or stock of any class of any company quoted on a recognised stock exchange) engage or be concerned or interested directly or indirectly in any other trade, business or occupation whatsoever.
- 2.2 Notwithstanding the provisions of clause 2.1 the Company shall:
  - (a) have the right to require the Executive at any time to carry out such special projects or functions commensurate with his abilities as the Company shall in its absolute discretion determine; and
  - (b) be under no obligation to assign to or vest in the Executive any powers, duties or functions or to provide any work for the Executive and may at any time suspend the Executive from the performance of any duties or exclude him from any premises of the Company. During the period of any such suspension or exclusion the Executive will remain an employee of the Company and may not work (whether or not for remuneration) for any other organisation (whether or not a competitor of the Company or any Associated Company) and the Company or any Associated Company or any Passociated Company or any person, firm or company who at the date of such suspension or exclusion is a client or customer of the Company or any Associated Company.
- 2.3 The Executive agrees that the maximum weekly working time as set out in regulation 4 of the Working Time Regulations 1998 shall not apply in relation to his employment. This condition shall apply indefinitely subject to the Executive's right to withdraw his agreement to the exclusion of the maximum weekly working time on providing three months' written notice.

## 3. REMUNERATION

3.1 As remuneration for his services hereunder the Company shall pay to the Executive a salary at the rate of two hundred thousand pounds (£200,000) per annum (which shall be deemed to accrue from day to day) payable in arrears by equal monthly instalments on the last day of each month such salary being inclusive of any fees to which the Executive may be entitled as a director of the Company or of any Associated Company. The said salary shall be reviewed by the Board from time to time. While a review does not imply any entitlement to an increase, the salary payable to the Executive may be increased with effect from any such review date.

3.2 For the purposes of the Employment Rights Act 1996 and otherwise the Executive hereby consents to the deduction of any sums owing by him to the Company at any time from his salary or any other payment due from the Company to the Executive and the Executive hereby also agrees to make any payment to the Company of any sums owed by him to the Company upon demand by the Company at any time.

## 4. PENSION AND INSURANCE BENEFITS

- 4.1 Subject to the allowances set by HM Revenue and Customs from time to time, the Company shall contribute at a rate equivalent to 10% of the Executive's basic monthly salary into a registered personal pension scheme of the Executive's choice.
- 4.2 As long as the Executive is employed by the Company, and conditional upon the Company being able to provide each of the benefits set out below, the Company shall pay premiums on behalf of the Executive up until the Executive reaches the age of 65 or state pension age, whichever is the higher, to provide medical insurance, permanent health insurance and life assurance. The Company shall have the right to change its arrangements for or withdraw the provision of such benefits as it sees fit providing always that it replaces such benefits with cover of substantial equivalence.
- 4.3 For the purposes of clause 4.2, participation in any such insurance scheme is:
  - (a) on the basis that the Company can give no assurance that any claim made will be accepted by the insurers of such scheme;
  - (b) on the basis that the Company shall not be required to take any steps to obtain the benefit of such scheme should the insurer either reject any claim and/or discontinue the payment of benefits at any time; and
  - (c) on the basis that the Company shall not be liable to pay any sums to or in respect of the Executive and/or his dependants unless the Company has received payment in full from the insurer.
- 4.4 The provision of the benefits at clause 4.2 shall not restrict the Company's ability to terminate the Executive's employment in accordance with clauses 1 or 12 of this Agreement for any reason including, without limitation, because the Executive is incapacitated.

#### 5. BONUS

5.1 The Executive is entitled to be considered for an annual bonus and the Company may, in its absolute discretion, pay to the Executive a bonus of such amount, if any, as the Board may determine provided that:

- (a) any such bonus may consist of or include securities and/or share options in the Company or any Group Company; and
- (b) if the Company makes a bonus payment to the Executive in respect of any bonus year, it shall not be obliged to make a bonus payment in any subsequent bonus year and the Executive agrees that he shall have no entitlement to receive such a payment; and
- (c) no bonus shall be paid if before the date on which the Company usually pays bonuses:
  - (i) notice of termination has been given by either party to the other; and/or
  - (ii) the Executive's employment under this Agreement is terminated for any reason; and/or
  - (iii) the Company has instituted disciplinary proceedings against the Executive or the Executive is subject to an unexpired disciplinary warning.

#### 6. EXPENSES

The Company shall reimburse to the Executive all travelling, hotel, entertainment and other expenses properly and reasonably incurred by him in the performance of his duties hereunder and properly claimed and vouched for (including production of appropriate receipts or other evidence) in accordance with the Company's expense reporting procedure in force from time to time.

## 7. HOLIDAYS AND HOLIDAY PAY

- 7.1 In addition to the normal Bank and public holidays the Executive shall be entitled to 28 working days' paid holiday during each calendar year to be taken at such time or times as may be agreed with the Board. The Executive may not without the consent of the Board carry forward any unused part of his holiday entitlement to a subsequent calendar year.
- 7.2 For the calendar year during which the Executive's employment hereunder commences or terminates he shall be entitled to such proportion of his annual holiday entitlement as the period of his employment in each such year bears to one calendar year. Upon termination of his employment for whatever reason he shall if appropriate either be entitled to salary in lieu of any outstanding holiday entitlement or be required to pay to the Company any salary received in respect of holiday taken in excess of his proportionate holiday entitlement.

#### 8. SICKNESS/INCAPACITY

8.1 If the Executive shall be prevented by illness, accident or other incapacity from properly performing his duties hereunder he shall report this fact forthwith to the Board and if he is so prevented for more than seven consecutive days he shall if required by the Company provide an appropriate doctor's certificate.

8.2 If the Executive shall be absent from his duties hereunder owing to illness, accident or other incapacity duly certified in accordance with the provisions of clause 8.1 he shall be paid his full remuneration for the first ten days of such absence and thereafter subject to the provisions of clause 12 such remuneration as the Board shall in its discretion allow provided that there shall be deducted from such remuneration any Statutory Sick Pay or any social security or other benefits payable to the Executive including any sums recoverable from a third party and any sums payable to the Executive under the permanent health insurance arrangement referred to in clause 4.1 above.

## 9. CONFIDENTIAL INFORMATION

- 9.1 The Executive shall not at any time during the course of his employment nor at any time after its termination except for a purpose of the Company or any Associated Company directly or indirectly use or disclose trade secrets or confidential information relating to the Company or any Associated Company or the Company's or any Associated Company's agents, customers, prospective customers or suppliers.
- 9.2 For the purposes of clause 9.1 confidential information shall include any information relating to the business and/or the financial affairs of the Company and/or any Associated Company and the Company's and/or any Associated Company's agents, customers, prospective customers or suppliers and in particular shall include:
  - (a) the business methods and information of the Company and any Associated Company (including prices charged, discounts given to customers or obtained from suppliers, product development, marketing and advertising programmes, costings, budgets, turnover, sales targets or other financial information);
  - (b) confidential details as to the design of the Company's and any Associated Company's products and Inventions or developments relating to future Inventions or products or details of its or their research development programs or plans;
  - (c) secret research, manufacturing or production processes and know-how employed by the Company and any Associated Company or its/their suppliers;
  - (d) details and terms of the Company's and any Associated Company's agreements with suppliers and customers and lists and particulars of the Company's and any Associated Company's suppliers and customers and the individual contacts at such suppliers and customers;
  - (e) details of any promotions or future promotions or marketing or publicity exercises planned by the Company and any Associated Company;
  - (f) details of any budgets or business plans of the Company and any Associated Company; and
  - (g) any information which may affect the value of the business or the shares of the Company or any Associated Company, whether or not in the case of documents or other written materials or any materials in electronic format they are or were marked as confidential and whether or not, in the case of other information, such information is identified or treated by the Company or any Associated Company as being confidential.

- 9.3 The Executive shall not be restrained from using or disclosing any confidential information which:
  - (a) he is authorised to use or disclose by the Board; or
  - (b) has entered the public domain unless it enters the public domain as a result of an unauthorised disclosure by the Executive or anyone else employed or engaged by the Company or any Associated Company; or
  - (c) he is required to disclose by law
- 9.4 The Executive shall not make copies of any document, memoranda, correspondence (including emails), computer disk, CD-ROM, memory stick, video tape or any similar matter (including for the avoidance of doubt in any electronic format) or remove any such items from the premises of the Company or of any Associated Company other than in the proper performance of his duties under this Agreement except with the Board's written authority which authority will apply in that instance only.

## 10. INTELLECTUAL PROPERTY

- 10.1 The parties acknowledge that the Executive is employed to create Inventions (alone or jointly) pursuant to his Development Duties in the course of his employment with the Company and that the Executive has a special obligation to further the interests of the Company in relation to such Inventions. The Executive shall, promptly following creation, disclose to the Company all such Inventions and works embodying Company Intellectual Property. It is further acknowledged that anything done by the Executive in furtherance of any program or development plan funded by the Company is intended to be Company Intellectual Property.
- 10.2 The Executive acknowledges that (except to the extent prohibited by or ineffective in law) all Company Intellectual Property and materials embodying them shall automatically belong to the Company as from creation for the full term of those rights and (except to the extent prohibited by or ineffective in law), the Executive hereby assigns, by way of present and future assignment, any and all right, title and interest therein to the Company.
- 10.3 To the extent that any Company Intellectual Property does not vest in the Company automatically pursuant to clause 10.2 (and except to the extent prohibited by or ineffective in law), the Executive holds such property on trust for the Company and hereby grants to the Company an exclusive, royalty free licence to use such property in its discretion until such Company Intellectual Property fully vests in the Company.

10.4 To the extent that any Inventions created by the Executive (whether alone or jointly) pursuant to his Development Duties at any time during the course of his employment are prohibited by or prevented in law from automatically vesting with the Company pursuant to clause 10.2, the Executive shall, immediately upon creation of such rights, grant the Company a right of first refusal, in writing, to acquire them on arm's length terms to be agreed between the parties. If the parties cannot agree on such terms within 30 days of the Company receiving the offer, the Company shall refer the dispute to an arbitrator who shall be appointed by the President of the Institute of Chartered Accountants in England and Wales. The arbitrator's decision shall be final and binding on the parties and the costs of arbitration shall be borne equally by the parties.

## 10.5 The Executive agrees:

- (a) to use reasonable endeavours to execute all such documents, both during and after the Appointment, as the Company may require to vest in the Company all right, title and interest in and to the Company Intellectual Property at the reasonable expense of the Company:
- (b) to use reasonable endeavours to, provide all such information and assistance and do all such further things as the Company may require to enable it to protect, maintain and exploit the Company Intellectual Property to the best advantage, at the reasonable expense of the Company, including (without limitation), at the Company's request, applying throughout the world for the protection of Inventions resulting from the Executive's Development Duties;
- (c) to use reasonable endeavours to assist the Company in applying for the registration of any registrable Company Intellectual Property, to enable it to enforce the Company Intellectual Property against third parties and to defend claims for infringement of third party Intellectual Property Rights by Company Intellectual Property at the reasonable expense of the Company:
- (d) not to apply for the registration of any Company Intellectual Property in the United Kingdom or any other part of the world without the prior written consent of the Company; and
- (e) to keep confidential all Company Intellectual Property unless the Company has consented in writing to its disclosure by the Executive.
- 10.6 As against the Company, its successors and assigns and any licensee of any of the foregoing, the Executive hereby waives all of his present and future moral rights which arise under the Copyright Designs and Patents Act 1988 and all similar rights in other jurisdictions relating to the Company Intellectual Property.
- 10.7 The Executive acknowledges that, except as provided by law, no further remuneration or compensation, other than that provided for in this Agreement, is or may become due to the Executive in respect of his compliance with this clause 10. This clause is without prejudice to the Executive's rights under the Patents Act 1977.
- 10.8 The Executive irrevocably appoints the Company as the Executive's attorney in the Executive's name to sign, execute, do or deliver on the Executive's behalf any deed, document or other instrument and to use the Executive's name for the purpose of giving full effect to this clause 10.

- 10.9 Rights and obligations under this Agreement shall continue in force after termination of this Agreement in respect of any Company Intellectual Property.
- 10.10 In this Agreement words defined below shall have the following respective meanings:

"Company Intellectual Property" means any and all Intellectual Property Rights created by the Executive (whether jointly or alone) resulting from the Executive's performance of the Development Duties, whether or not during working hours or using Company premises or resources and whether or not recorded in material form;

"Intellectual Property Rights" means patents, Inventions, copyright and related rights, trade marks, trade names, service marks and domain names, rights in get-up, goodwill, rights to sue for passing off, design rights, semi-conductor topography rights, database rights, confidential information, moral rights, proprietary rights and any other intellectual property rights in each case whether registered or unregistered and including all applications or rights to apply for, and renewals or extensions of such rights and all similar or equivalent rights or forms of protection which subsist or will subsist now or in the future in any part of the world; and

"Invention" means any invention, idea, discovery, development, improvement or innovation, processes, formulae, models or prototypes, whether or not patentable or capable of registration, and whether or not recorded in any medium.

#### 11. RESTRICTIVE COVENANTS

- 11.1 Since the Executive will in the course of his employment hereunder have dealings with customers and obtain knowledge of the trade secrets and other confidential information in regard to the business of the Company and its Associated Companies, the Executive hereby agrees and undertakes with the Company for itself and as trustee for its Associated Companies that he shall not without the prior written consent of the Board (such consent to be withheld only so far as may be reasonably necessary to protect the legitimate interests of the Company or any Associated Company):
  - (a) for a period of 12 months after the termination of his employment hereunder be engaged or interested (whether as a director, shareholder, principal, consultant, agent, partner or employee or otherwise) in any business concern (of whatever kind) which shall in the United Kingdom be in competition with the Company or with any Associated Company in the provision of services relating to gene therapy or the manufacture, sale or supply of goods relating to gene therapy, being services or goods of a kind with which the Executive was concerned to a material extent during the period of one year prior to the termination of his employment with the Company provided always that nothing in this clause (a) shall restrain the Executive from engaging or being interested as aforesaid in any such business concern in so far as his duties or work relate principally to services or goods of a kind with which the Executive was not concerned during the period of one year prior to the termination of his employment hereunder;

- (b) for a period of 12 months after the termination of his employment hereunder either on his own behalf or on behalf of any other person, firm or company in respect of any services of a kind provided relating to gene therapies of a kind developed or licensed by the Company or any goods of a kind similar to or the same as those sold or supplied by the Company and/or any Associated Company relating to gene therapies of a kind developed or licensed by the Company in respect of the provision or sale or supply of which the Executive may have been engaged during his employment with the Company or any Associated Company:
  - (i) canvass, solicit or approach or cause to be canvassed, solicited or approached for orders; or
  - (ii) directly or indirectly deal with any person, firm or company who at the date of the termination of this Agreement or within one year prior to such date is or was a client or customer of the Company or any Associated Company or was in the habit of dealing under contract with the Company or any Associated Company and with whom or which the Executive had provided or arranged the provision of service or services on behalf of the Company or any Associated Company or for whom the Executive had management responsibility or material contact with during the period of one year prior to the termination of this Agreement; and
- (c) for a period of 12 months after the termination of his employment hereunder either on his own behalf or on behalf of any other person, firm or company directly or indirectly solicit or entice or endeavour to solicit or entice away from the Company or from any Associated Company any employee of executive or managerial status engaged in its or their business and with whom the Executive had dealings at any time during the last year of his employment hereunder.
- 11.2 Whilst each of the restrictions in clauses 11.1(a), 11.1(b) and 11.1(c) are considered by the parties to be reasonable in all the circumstances as at the date hereof it is hereby agreed and declared that if any one or more of such restrictions shall be judged to be void as going beyond what is reasonable in all the circumstances for the protection of the interests of the Company and/or any Associated Company but would be valid if words were deleted therefrom the said restrictions shall be deemed to apply with such modifications as may be necessary to make them valid and effective and any such modification shall not thereby affect the validity of any other restriction contained herein.

## 12. TERMINATION ON THE HAPPENING OF CERTAIN EVENTS

12.1 The Company reserves the right in its absolute discretion and at any time (including after notice of termination has been served by either party) to terminate the Executive's employment with immediate effect by notifying the Executive that it is exercising its rights under this clause and that within 28 days it will make a payment in lieu of the notice entitlement referred to in clause 1 or if less, any unexpired period of notice of termination. Such a payment in lieu shall consist of a sum equivalent to the Executive's annual salary only for the relevant period.

- 12.2 The Company without prejudice to any remedy which it may have against the Executive for the breach or non-performance of any of the provisions of this Agreement may forthwith terminate this Agreement without notice or payment in lieu of notice if the Executive:
  - (a) becomes bankrupt or become the subject of an interim order under the Insolvency Act 1986 or make any arrangement or composition with his creditors; or
  - (b) becomes of unsound mind or a patient as defined in the Mental Health Act 1983; or
  - (c) is convicted of any criminal offence (other than an offence under road traffic legislation in the United Kingdom or elsewhere for which a penalty other than imprisonment for three months or more is imposed); or
  - (d) commits any act of dishonesty, fraud or corruption whether relating to the Company, any Associated Company, other employees or otherwise; or
  - (e) is prevented by illness or otherwise from performing his duties hereunder for a consecutive period of six calendar months or for an aggregate period of six calendar months in any period of 12 calendar months; or
  - (f) is guilty of any gross or serious misconduct, any conduct tending to bring the Company or himself into disrepute, or any material breach or non-observance of any of the provisions of this Agreement or shall neglect, fail or refuse to carry out duties properly assigned to him hereunder.

## 13. OBLIGATIONS UPON TERMINATION OF EMPLOYMENT

- 13.1 Upon the termination of his employment hereunder for whatever reason, or upon the Company's exercise of its rights under clauses 13.1(a) and 13.1(b) at any time after notice of termination has been given under clause 1, the Executive shall:
  - (a) forthwith tender his resignation as a Director of the Company and of any Associated Company without compensation. To secure his obligation under this Agreement the Executive irrevocably appoints the Company to be his attorney in his name and on his behalf to sign any documents and do any things necessary to give effect thereto, if the Executive shall fail to sign or do the same himself;
  - (b) deliver up to the Company all vehicles, keys, credit cards, correspondence, documents, specifications, reports, papers and records (including any computer materials such as discs or tapes) and all copies thereof and any other property (whether or not similar to the foregoing or any of them) belonging to the Company or any Associated Company which may be in his possession or under his control,

and (unless prevented by the owner thereof) any such property belonging to others which may be in his possession or under his control and which relates in any way to the business or affairs of the Company or any Associated Company or any supplier, agent, distributor or customer of the Company or any Associated Company, and he shall not without written consent of the Board retain any copies thereof;

- (c) if so requested send to the Company a signed statement confirming that he has complied with clause 13.1(b); and
- (d) not at any time represent himself still to be connected with the Company or any Associated Company.

## 14. GARDEN LEAVE

- 14.1 Notwithstanding the provisions of clause 2.1, following the Company or the Executive giving notice to terminate the Executive's employment or if the Executive purports to terminate his employment in breach of contract, the Company may require the Executive not to perform any services (or to perform only specified services) for the Company or for any Associated Company for all or part of the applicable notice period required under clause 1.
- 14.2 During any period where the Company exercises its rights under clause 14.1 above, the Executive shall:
  - (a) continue to receive his salary and other contractual benefits under this Agreement in the usual way and subject to the terms of any benefit arrangements;
  - (b) remain an employee of the Company and remain bound by his duties and obligations, whether under this Agreement or otherwise, which shall continue in full force and effect;
  - (c) not contact or deal with (or attempt to contact or deal with) any customer client supplier agent distributor shareholder employee officer or other business contact of the Company or any Associated Company;
  - (d) not (unless otherwise requested) enter onto the premises of the Company or any Associated Company;
  - (e) not commence any other employment or engagement (including taking up any directorships or consultancy services;
  - (f) provide such reasonable assistance as the Company or any Associated Company may require to effect an orderly handover of his responsibilities to any individual or individuals appointed by the Company or any Associated Company to take over his role or responsibilities; and

- (g) make himself reasonably available to deal with requests for information, to provide assistance, to attend meetings and to advise on matters relating to the Company's business.
- 14.3 In the event that the Company exercises its rights under clause 14.1 above then any period of time this relates to shall be set off against and therefore reduce the periods for which the restrictions in clause 11.1 of this Agreement apply.

#### 15. OTHER TERMS AND CONDITIONS

- 15.1 The following particulars are given in compliance with the requirements of s 1 Employment Rights Act 1996:
  - (a) the Executive's normal place of work is UCLB, 97 Tottenham Court Road, London W1T 4TP but he may be required to work at any other office or location in the UK as may be directed by the Board from time to time;
  - (b) the Executive's continuous employment began on April 27th, 2015. No employment of the Executive with a previous employer counts as part of the Executive's continuous employment with the Company;
  - (c) the Executive's hours of work shall be the normal hours of work of the Company which are from [insert-time] am to [insert time] pm together with such additional hours as may be necessary for the proper discharge of his duties hereunder to the satisfaction of the Board;
  - (d) if the Executive is dissatisfied with any disciplinary decision or if he has any grievance relating to his employment hereunder he should refer such disciplinary decision or grievance to the Board and the reference will be dealt with by discussion at and decision of a Board Meeting;
  - (e) no contracting-out certificate pursuant to the provisions of Pension Schemes Act 1993 is in force in respect of the Executive's employment hereunder; and
  - (f) save as otherwise herein provided there are no terms or conditions of employment relating to hours of work or to normal working hours or to entitlement to holiday (including public holidays) or holiday pay or to incapacity for work due to sickness or injury or to pensions or pension schemes and no collective agreement has any effect upon the Executive's employment hereunder.

## 16. DEFINITION

In this Agreement an "Associated Company" means any company which for the time being is:

(a) a parent undertaking (as defined by the Companies Act 2006) of the Company; or

(b) any subsidiary undertaking (as defined by the Companies Act 2006) of any such parent company or of the Company.

## 17. MISCELLANEOUS

A person, firm or company who or that is not a party to this Agreement shall have no right under the Contracts (Rights of Third Parties) Act 1999 to enforce any term of this Agreement.

## 18. APPLICABLE LAW

English law shall apply to this Agreement and the parties submit to the jurisdiction of the English Courts.

<b>IN WITNESS</b> whereof this deed has been duly executed and delivered the day and year first before written		
Executed as a deed by	)	Athena Vision Limited
acting by:	)	
/s/ Rich Giroux	_	
Director		
/s/ Tom Shenk	_	
Director Secretary		
Sign as a deed by	)	
In the presence of	)	RG
/s/ Sury Penny	_	
Witness' signature		
Sury Penny	_	
Witness' name		
Hogan Lovells International LLP		
DX57		
LONDON CHANCERY LANE		

Witness' address

## LICENSE AGREEMENT

between

## **BRANDEIS UNIVERSITY**

and

## **BRI-Alzan Inc.**

Confidential Portions of this Exhibit marked as [\*\*\*] have been omitted pursuant to a request for confidential treatment and have been filed separately with the Securities and Exchange Commission.

## LICENSE AGREEMENT

This License Agreement ("Agreement"), effective as of May 1, 2013 ("Effective Date") between Brandeis University, a not-for-profit corporation duly organized and existing under the laws of The Commonwealth of Massachusetts and having its principal place of business at 415 South Street, Waltham, Massachusetts 02454-9110 ("Brandeis"), and BRI-Alzan Inc., a corporation duly organized and existing under the laws of the State of Delaware and having offices at c/o Fidelity Biosciences Corp., One Main Street, 13th Floor, Cambridge, MA 02142 (hereinafter referred to as "Licensee").

WHEREAS, Brandeis through research conducted by Dagmar Ringe, Gregory Petsko and Xu Simon (the "Inventors"), has developed an invention pertaining to by Brandeis Case No. 1092 "Protein Therapy for ALS", for which Brandeis has filed patent applications.

WHEREAS, as a center for research and education, Brandeis desires to license the Patent Rights and thus benefit the public and Brandeis by facilitating the dissemination of the results of its research in the form of useful products. However, Brandeis itself does not have the capacity to commercially develop, manufacture or distribute the Licensed Products, and is therefore willing to grant an exclusive license to the Licensee in the technology.

WHEREAS, Licensee having such capacity, desires to commercially develop, manufacture, use and distribute such Licensed Products.

WHEREAS, Brandeis and Fidelity Biosciences Corp, (as defined herein) have entered into a Research Agreement (as defined herein) and Brandeis and Fidelity Biosciences Corp, have acknowledged that this Agreement is an Alternative Arrangement (as defined in the Research Agreement), which shall be in lieu of and not in addition to the license set forth in the Research Agreement.

NOW THEREFORE, in consideration of the mutual covenants of this Agreement, the parties agree:

#### 1. DEFINITIONS

- 1.1 "Accounting Period" means each three month period during the term of this Agreement, including partial periods at the beginning and end of the term of this Agreement, ending March 31, June 30, September 30 and December 31.
- 1.2 "Affiliate" means, with respect to any specified Person, any other Person who, directly or indirectly, Controls, is Controlled by, or is under common Control with such Person, including without limitation any entity that is a general partner or managing member of such Person. The term "Control" of a given Person means possession, direct or indirect, of the power to direct the management or policies of such Person, directly or indirectly, whether through the ownership of voting securities, by contract or otherwise, and the terms "Controlling" and "Controlled" shall have meanings correlative to the foregoing.

#### 1.3 [Reserved]

Confidential Portions of this Exhibit marked as [\*\*\*] have been omitted pursuant to a request for confidential treatment and have been filed separately with the Securities and Exchange Commission.

- 1.4 "Change of Control" means transfer of all, or substantially all, of the rights granted in the Agreement to a non-Affiliate assignee, in accordance with Section 10.4, hereunder, or to a Sublicensee in accordance with Section 2.2, hereunder.
  - 1.5 "Fidelity Biosciences" means Fidelity Biosciences Corp. ("FBC"), a Delaware corporation.
  - 1.6 "First Commercial Sale" means the first sale of any Licensed Product by Licensee or its Affiliates or its Sublicensees (each, a "Seller").
- 1.7 "Gross Sales" or "Gross Sales Price" means for any arm's length sale, transfer, dispositions or other dealing to a customer by a Seller, the Gross Sales Price shall be the gross amount invoiced by the Seller for the sale, transfer or other disposition of or dealing with a Licensed Product.

Transfer of a Licensed Product within the Licensee or between Licensee, Sublicensee or an Affiliate shall not be considered a sale, commercial use or disposition for the purpose of the foregoing paragraphs; in the case of such transfer the Gross Sales Price shall be based on sale of the Licensed Product by the transferee. If a Seller commercially uses or disposes of any Licensed Product by itself other than in an arm's length sale to a bona fide customer, the Gross Sales Price hereunder shall be the price which would be then payable in an arm's length transaction. [\*\*\*].

For any sale of a Licensed Product to which the United States government is entitled to a royalty-free right pursuant to 35 USC 202(c)(paragraph 4), [\*\*\*].

- 1.8 "Know-How" means Brandeis' rights in discoveries, data (including research, pre-clinical and clinical data), designs, formulas, methods, techniques, materials, technology, results, analyses, and process information (including scientific and technical information) or know-how during the term of this Agreement that are not claimed by the Patent Rights but are, or could reasonably be, necessary for practicing the Patent Rights.
  - 1.9 "License Fields" mean all fields.
- 1.10 "Licensed Products" mean any composition or method, the practice, development, manufacture, use, offer for sale or sale of which, in whole or in part absent the licenses granted herein, would infringe a Valid Claim of any Patent Right.
  - 1.11 "NDA Filing" means filing a New Drug Application with the USFDA for a Licensed Product.
- 1.12 "Net Sales" or "Net Sales Price" means the Gross Sales Price received by a Seller less (to the extent appropriately documented) the following amounts actually paid out by a Seller or credited against the amounts received by it from the sale or distribution of Licensed Product:
- (a) credits, allowances and price adjustments for damaged Licensed Products or for the rejection or return of Licensed Products previously sold; Confidential Portions of this Exhibit marked as [\*\*\*] have been omitted pursuant to a request for confidential treatment and have been filed separately with the Securities and Exchange Commission.

- (b) rebates, chargeback payments and trade, cash and quantity discounts to purchasers allowed and taken;
- (c) amounts for transportation, insurance, handling or shipping charges directly related to the sale or distribution of Licensed Product and listed on the invoices or purchase order for such Licensed Product; and
- (d) taxes, tariffs, duties and other governmental charges levied on or measured by the sale of Licensed Products, whether absorbed by the Seller or paid by the purchaser so long as the Seller's price is reduced thereby, but not franchise or income taxes of any kind whatsoever.
- 1.13 "Patent Right" means Brandeis' rights in patents and patent applications listed in Exhibit B, (the "Applications"), or the equivalent of such Applications, including any division, continuation or any foreign patent application; and any Letters Patent or the foreign equivalent issuing on such applications, and any reexamination or extension thereof. Patent Rights shall also include those claims in any continuation-in-part application that are supported or enabled by the Applications. All of the Inventors' rights, title and interest in the Applications have been assigned to Brandeis.
  - 1.14 "Person" means any corporation, partnership, trust, or limited liability company, association or other entity.
  - 1.15 "Phase II Initiation" means the first dosing of a human subject, in Phase II (Phase Two) Clinical Trials, with a Licensed Product.
  - 1.16 "Phase III Initiation" means the first dosing of a human subject, in Phase III (Phase Three) Clinical Trials, with a Licensed Product.
  - 1.17 "Research Agreement" means the Research Agreement between Brandeis and Fidelity Biosciences, dated as of December 21, 2011.
  - 1.18 "Research Agreement Term" means the effective term of the Research Agreement.
  - 1.19 "Seller" has the meaning set forth in Section 1.6.
- 1.20 "Sublicensee" means any non-Affiliate third party licensed by Licensee or an Affiliate in accordance with Section 2.2 to develop, commercialize, make, have made, use, lease, import, sell or offer for sale any Licensed Product.
  - 1.21 "Territory" shall mean world-wide.
- 1.22 "Valid Claim" means any claim of any Patent Right that has not been (i) finally rejected or (ii) declared invalid by a patent office or court of competent jurisdiction in any unappealed and unappealable decision.

Confidential Portions of this Exhibit marked as [\*\*\*] have been omitted pursuant to a request for confidential treatment and have been filed separately with the Securities and Exchange Commission.

#### 2. LICENSE

- 2.1 <u>Grant of License</u>. To the extent not prohibited by the United States Government or by contractual obligations to any other sponsor of research at Brandeis, and expressly subject to Sections 2.3 through 2.6 below as well as the other terms and conditions of this Agreement, Brandeis hereby grants Licensee:
- 2.1.1 an exclusive, terminable, royalty-bearing license under Patent Rights to develop, commercialize, make, have made, use, lease, import, sell and offer for sale Licensed Products solely in the License Fields in the Territory; and
- 2.1.2 A non-exclusive, terminable, royalty-free license to use the Know-How, solely to the extent necessary to practice the exclusive rights under Section 2.1.1, above.
- All licenses pursuant to this Section 2.1 are subject to the rights, conditions and limitations imposed by U.S. law with respect to inventions made in the performance of federally funded research.
- 2.2 <u>Right to Sublicense</u>. Brandeis grants to Licensee the right to grant sublicenses in its rights, privileges and license granted to Licensee in Section 2.1, only with the prior written approval of Brandeis, which permission shall not be unreasonably withheld.
- 2.2.1 Sublicenses granted under this Section shall contain all of the conditions, restrictions and reservations of this Agreement, except for the provisions related to fees and royalties, and must preserve the rights of Brandeis and the U.S. Government existing under this Agreement. Licensee shall promptly provide to Brandeis a copy of any and all fully executed sublicense agreements, and shall provide to Brandeis, within [\*\*\*] ([\*\*\*]) days of the end of each Accounting Period, a copy of reports received by Licensee from its Sublicensees for the previous Accounting Period relating to royalty or non-royalty consideration under such sublicense agreements.

<u>2.2.2</u> [\*\*\*].

- 2.2.3 The granting of a sublicense by Licensee shall not operate to relieve Licensee from any of its obligations under this Agreement. Licensee shall be responsible for and remit royalties based upon its Sublicensee's activities as if said activities were its own.
- 2.3 Reservation of Rights. Brandeis expressly reserves the right to make, have made and to use and transfer the subject matter described and claimed in the Patent Rights for any noncommercial purpose.
  - 2.4 [\*\*\*] Manufacturing. Licensee agrees that [\*\*\*].
- <u>2.5</u> <u>Scope</u>. Nothing herein shall be construed to grant Licensee a license, express or implied, under any intellectual property right owned solely or jointly by Brandeis other than the Patent Rights and Know-How expressly licensed hereunder.

- 2.6 Affiliates. Licensee may extend the license granted herein to any Affiliate of Licensee if the Affiliate consents in writing to be bound by this Agreement to the same extent as Licensee. Licensee must deliver to Brandeis a true and accurate copy of such written agreement, and any modification or termination thereof, within [\*\*\*] days after execution, modification or termination.
- 2.7 <u>Liability</u>. Notwithstanding any liability that may accrue directly to any Affiliate or Sublicensee hereunder, Licensee shall remain directly liable to Brandeis for any amount due from or liability incurred or accrued by any Sublicensee or Affiliate under this Agreement.
- 2.8 <u>Representation</u>. Brandeis represents, to the best of its knowledge, that all of the Inventors' rights, title and interest in the Applications have been assigned to Brandeis. Licensee acknowledges receipt of copies of the patent assignments from Brandeis.

#### 3. DILIGENCE OBLIGATIONS

- 3.1 <u>Commercialization Milestones</u>. Licensee shall itself, or through its Affiliates or Sublicensees, use commercially reasonable efforts to develop Licensed Products for commercial sales and distribution in the License Fields in the Territory and to continue active, diligent marketing efforts for Licensed Products throughout the life of this Agreement. Such efforts require achieving the following objectives:
- (a) During the last [\*\*\*] ([\*\*\*]) months of the Research Agreement Term, the parties will meet and mutually agree on due dates for the following milestones. These milestone due dates shall be incorporated into this agreement:

Milestone

Achievement Due Date (to be added in accordance with this Section 3.1(a)

- (i) Phase II Initiation
- (ii) Phase III Initiation
- (iii) NDA Filing

If Licensee fails to achieve one or more of the above objectives within the above stated periods, Brandeis, in its sole discretion, shall have the right to terminate any exclusive or nonexclusive license granted hereunder in accordance with Section 9.2.1, below.

- 3.2 <u>Progress Reports</u>. Within [\*\*\*] ([\*\*\*]) days of the end of its fiscal year, Licensee shall provide a written report to Brandeis detailing its progress or lack of progress, along with supporting documentation, made toward the foregoing objectives.
- 3.3 Research Agreement. The parties acknowledge that the Research Agreement was signed December 21, 2011, and that FBC has paid all fees due under the Research Agreement to date.

## 4. PAYMENTS AND REPORTS

- 4.1 Fees and Royalties. In consideration for the rights, privileges and license granted under this Agreement, Licensee shall pay to Brandeis the fees, equity and royalties set forth in Exhibit A. In each year the amount of royalty and sublicense fees due shall be calculated quarterly as of the end of each Accounting Period and shall be paid within [\*\*\*] ([\*\*\*]) days following the end of such Accounting Period.
- 4.2 <u>Late Payments</u>. If any payment due under this Agreement is not paid within [\*\*\*] ([\*\*\*]) days of the date upon which such payment is due, then interest shall accrue on such payment on a daily basis from the date such payment was originally due at a rate equal to [\*\*\*] ([\*\*\*]) month LIBOR (as published in The Wall Street Journal, New York edition) plus [\*\*\*] percent ([\*\*\*]%) per annum, calculated daily, or at the maximum rate permitted by law, whichever is the lower, and such interest shall be paid when such payment is made. The payment of such interest shall not preclude the party receiving such interest from exercising any other rights it may have as a consequence of the lateness of any payment.
- 4.3 Conversion. All amounts payable by Licensee must be paid in United States dollars without deductions for taxes, assessments, fees, or charges of any kind. Royalties accruing on sales in countries other than the United States must be paid in United States dollars in amounts based on the rate of exchange as quoted in the Wall Street Journal (WSJ) as of the last business day of the reporting period. If the WSJ does not publish any such rate, a comparable rate publication will be agreed upon from time to time by the parties, and with respect to each country for which such rate is not published by the WSJ or in a comparable publication, the parties will use the prevailing rate for bank cable transfers for such date, as quoted by leading United States banks in Boston dealing in the foreign exchange market.
- 4.4 Records. Licensee shall keep complete and accurate records of its, and its Affiliates and Sublicensees' Net Sales under the license granted in this Agreement in sufficient detail to enable the royalties payable hereunder to be determined. Such records shall be retained for at least [\*\*\*] ([\*\*\*]) years following the end of the Accounting Period to which such records relate. Licensee agrees to permit Brandeis or its representatives, at Brandeis' expense and with [\*\*\*] days written notice, to periodically examine its books, ledgers, and records during regular business hours for the purpose of and to the extent necessary to verify any report and payment required under this Agreement. If the amounts due to Brandeis are determined to have been underpaid, by [\*\*\*] percent ([\*\*\*]%) or more, Licensee will pay the cost of the examination and all overdue amounts with accrued interest in accordance with Section 4.2.
- 4.5 Royalty Reports. Whether or not a payment is due, Licensee shall deliver to Brandeis a full and accurate reporting and accounting, certified as such by an officer of Licensee, as well as supporting documents as required by Sections 2.2, 2.6 and 3.2 and this Section 4.5 regarding any royalties or other consideration, and shall include at least the following information for the preceding Accounting Period within [\*\*\*] ([\*\*\*]) days of the end of the preceding Accounting Period:
  - 4.5.1 Quantity of each Licensed Product sold (by country) by the Sellers;

- 4.5.2 Total billings for each Licensed Product (by country);
- 4.5.3 Quantities of each Licensed Product used by Licensee and its Affiliates or Sublicensees;
- 4.5.4 An accounting of all deductions applicable to determine the Net Sales;
- 4.5.5 Names and addresses of all Sublicensees and Affiliates subject to Section 2.6 of Licensee; and
- 4.5.6 Total royalties payable to Brandeis.
- 4.6 Annual Reports. Licensee shall deliver to Brandeis a copy of its financial statements, certified by an officer of Licensee, and evidence or renewal of insurance in accordance with Section 7.2, below, within [\*\*\*] ([\*\*\*]) days of the end of its fiscal year. Licensee shall deliver to Brandeis its annual reports to stock holders and material revisions to its business plan when prepared.
- 4.7 <u>Delivery</u>. All payments and reports due Brandeis shall be made payable to Brandeis University, shall include documentation as described in this Section 4 and reference to Brandeis Reference # 1092, and delivered to:

Director, Office of Technology Licensing Brandeis University, MS115 415 South Street Waltham, MA 02454-9110

## 5. FILING, PROSECUTION AND MAINTENANCE OF PATIENT RIGHT

5.1 Responsibility; Costs. Brandeis shall be responsible for the searching, preparation, filing, prosecution and maintenance of all patent applications and patents included in Patent Rights. Brandeis retains the right to select the attorney responsible for the prosecution and maintenance of the Patent Rights and to present such attorney to Licensee's approval which shall not be unreasonably withheld or delayed. The attorney responsible for the prosecution and maintenance of the Patent Rights shall be retained by mutual agreement of Brandeis and Licensee. Brandeis or its attorneys shall consult with Licensee with respect to all proposed actions and filings described in this Section 5.1 and shall provide Licensee with reasonable opportunities to advise Brandeis concerning the same. Licensee shall take reasonable actions to cooperate with Brandeis in such filing, prosecution and maintenance. Licensee shall reimburse Brandeis for all reasonable costs incurred by Brandeis for the preparation, filing, prosecution and maintenance of all Patent Rights ("Costs") as follows:

5.1.1 Subject to paragraph 5.1, above, for all Costs incurred by Brandeis prior to and after the Effective Date, Licensee shall reimburse Brandeis within [\*\*\*] ([\*\*\*]) days of receipt of invoices from Brandeis. Brandeis shall prepare, file, prosecute, and maintain all of the licensed Patent Rights. Brandeis and its appointed patent attorneys will [\*\*\*] copy Licensee on all patent correspondence as follows: (a) documents received from any patent office shall be provided to Licensee promptly after receipt; (b) any document to be filed in any patent office

shall be provided in draft form to Licensee sufficiently prior to such document's filing to allow for review and comment by Licensee; and (c) documents filed with any patent office shall be provided to Licensee promptly after filing. Licensee shall have reasonable opportunities to advise Brandeis and shall cooperate with Brandeis in such filing, prosecution and maintenance. Brandeis will cooperate with Licensee to manage patent costs.

## 6. INFRINGEMENT

- 6.1 Notice. If Licensee becomes aware of any actual, potential, or threatened infringement, misappropriation, act of unfair competition, or other harmful or wrongful activities of third parties with respect to the Patent Rights, Licensee shall, with reasonable promptness, notify Brandeis and provide relevant information and documentation. Licensee will not notify a third party of the infringement of any Patent Rights without first obtaining consent of Brandeis.
- 6.2 Enforcement by Licensee. So long as Licensee remains the exclusive licensee of the Patent Rights in the License Fields in the Territory, Licensee, to the extent permitted by law, shall have the right, under its own control and at its own expense, to prosecute any third party infringement of the Patent Rights in the License Fields in the Territory, subject to Sections 6.2.1 and 6.2.2, below. If required by law, Brandeis shall permit any action under this Section to be brought in its name, including being joined as a party-plaintiff, provided that Licensee shall hold Brandeis harmless from, and indemnify Brandeis against, any costs, expense or liability that Brandeis incurs in connection with such action; provided that Licensee shall not be obligated to indemnify Brandeis against any liability under this Section 6.2 that Brandeis incurs as a result of its own gross negligence or willful misconduct as determined by a court of final adjudication after exhaustion of all available appeals.

Prior to commencing any action, Licensee shall consult with Brandeis and shall consider the views of Brandeis regarding the advisability of the proposed action and its effect on the public interest. Licensee shall not enter into any settlement, consent, judgment or other voluntary final disposition of any infringement action under this Section without the prior written consent of Brandeis.

- 6.2.1 Payment of Royalties. If Licensee brings an action under this Section 6.2, Licensee may deduct from its royalty payments due to Brandeis pursuant to Exhibit A.1, an amount not to exceed [\*\*\*] percent ([\*\*\*]%) of Licensee's documented and actually paid or currently outstanding, costs and expenses of such action, including reasonable attorneys' fees, up to a total of [\*\*\*] percent ([\*\*\*]%) of the total royalty due to Brandeis in any Accounting Period.
- <u>6.2.2</u> <u>Treatment of Proceeds</u>. Any recovery or damages for past infringement derived therefrom or any amounts paid as a result of a settlement agreement (the "Gross Proceeds") shall be applied first in satisfaction of any unreimbursed expenses and reasonable legal fees of the parties,. [\*\*\*].
- 6.3 Enforcement by Brandeis. In the event that Licensee is unsuccessful in persuading the alleged infringer to desist or fails to have initiated an infringement action within [\*\*\*] ([\*\*\*]) months after Licensee first becomes aware of the basis for such action, Brandeis shall have the right, at its sole discretion, to prosecute such infringement under its sole control and at its sole expense, and any recovery obtained shall belong to Brandeis.

- 6.4 Actions for Declaratory Judgment. If a declaratory judgment action alleging invalidity or infringement of any of the Patent Rights is brought against Licensee, Brandeis, within [\*\*\*] ([\*\*\*]) days of being notified of such action, in its sole discretion, shall have the right (but not the obligation) to intervene and take over the sole defense of the action at its own expense. Licensee shall cooperate fully with Brandeis in connection with any such action. Any recovery of damages by Brandeis shall be applied first in satisfaction of any unreimbursed expenses of both Brandeis and Licensee. If Brandeis elects not to intervene, Licensee may assume the defense and may escrow royalties, otherwise due Brandeis pursuant to Section 6.2.1 and apportion damages in the same proportions and to the same extent as set forth in Section 6.2.2 hereof. [\*\*\*].
- <u>6.5 Cooperation</u>. In any infringement suit as either party may institute to enforce Patent Rights or in any defense of Patent Rights pursuant to this Agreement, the other party hereto shall, at the request and expense of the party initiating such suit, cooperate in all respects to the extent reasonably possible.
- 6.6 Non-Assert. Notwithstanding other provisions of this Article 6, Licensee (including its Affiliates and Sublicensees) and Brandeis agree that the Patent Rights shall not be asserted against not-for-profit research institutions for use on research funded by the institutions themselves, by not-for-profit foundations, by the Howard Hughes Medical Institute, by any state government, or by the Federal Government. Licensee may assert the Patent Rights [\*\*\*], and may assert the Patent Rights [\*\*\*].
- <u>6.7 Survival</u>. The provisions of this Section 6 shall survive any termination of this Agreement but only in respect of proceedings commenced prior to the date of termination for alleged or actual acts of infringements occurring during the term of this Agreement.

## 7. INDEMNIFICATION; INSURANCE

7.1 By Licensee. Licensee shall indemnify, defend and hold harmless Brandeis, and its current or former trustees, officers, governing board members, faculty, professional staff, employees, students, agents and Affiliates, and their respective successors, heirs and assigns (collectively, "Indemnitees"), against any and all liability, damage, loss, claim or expense (including legal expenses and reasonable attorneys' fees) incurred by or imposed upon the Indemnitees or any one of them in connection with any claims, suits, actions, demands or judgments arising out of or in connection with the transport, handling, research, development, design, manufacture, commercialization, marketing, sale, use, lease, consumption or advertisement of Licensed Products, including any actual or alleged injury, damage, death or other consequence occurring to any persons or property, and including against any claim that activities under this License Agreement infringe a third party's intellectual property rights, and against any other claim, proceeding, demand, expense and liability of any kind whatsoever (including, without limitation, actions in the form of tort warranty, or strict liability) resulting, directly or indirectly, from the possession, use or consumption of any Licensed Products or arising from any obligation of Licensee hereunder; provided that Licensee shall not be obligated

to indemnify the Indemnitees against any liability under this Section 7.1 that the Indemnitees incur as a result of their own gross negligence or willful misconduct as determined by a court of final adjudication after exhaustion of all available appeals. Licensee shall, at its own expense, provide attorneys reasonably acceptable to Brandeis to defend against any actions brought or filed against any Indemnitee hereunder with respect to the subject of indemnity contained herein, whether or not such actions are rightfully brought.

- 7.2 <u>Insurance</u>. Prior to first dosing of humans in a Phase I clinical trial with Licensed Product, Licensee shall, at its sole cost and expense, procure and maintain, or cause to be maintained (i) commercial general liability insurance, on an occurrence basis, in amounts not less than \$[\*\*\*] per occurrence and \$[\*\*\*] annual aggregate and, (ii) product liability insurance in amounts not less than \$[\*\*\*] per claim and \$[\*\*\*] annual aggregate. Such insurance policies shall (i) be through an insurance company with an A.M. Best minimum rating of [\*\*\*]; (ii) name the Indemnitees as additional insureds; (iii) [\*\*\*]; and (iv) [\*\*\*]. The minimum amounts of insurance coverage required under this Section 7.2 shall not be construed to create a limit of Licensee's liability with respect to its indemnification under Section 7.1.
- 7.2.1 Licensee shall provide Brandeis with an acceptable certificate as written evidence of such insurance prior to the use in humans of any Licensed Product. Licensee shall provide Brandeis with written notice at least [\*\*\*] ([\*\*\*]) days prior to the cancellation, nonrenewal or material reduction in such insurance; if Licensee does not obtain replacement insurance providing comparable coverage prior to the expiration of such [\*\*\*] ([\*\*\*]) day period, Brandeis shall have the right to terminate this Agreement effective at the end of such [\*\*\*] ([\*\*\*]) day period without notice or any additional waiting periods.
- 7.2.2 Licensee shall maintain such insurance beyond the expiration or termination of this Agreement during (i) the period that any such Licensed Product, process, or service is being commercially distributed or sold by any Seller and (ii) a reasonable period after the period referred to in (i) but in no event less than [\*\*\*].
- 7.3 IN NO EVENT SHALL BRANDEIS BE LIABLE FOR ANY INDIRECT, SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES (INCLUDING, WITHOUT LIMITATION, DAMAGES FOR LOSS OF PROFITS OR EXPECTED SAVINGS OR OTHER ECONOMIC LOSSES, OR FOR INJURY TO PERSONS OR PROPERTY) ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT OR ITS SUBJECT MATTER, REGARDLESS OF WHETHER BRANDEIS KNOWS OR SHOULD KNOW OF THE POSSIBILITY OF SUCH DAMAGES. BRANDEIS' AGGREGATE LIABILITY FOR ALL DAMAGES OF ANY KIND RELATING TO THIS AGREEMENT OR ITS SUBJECT MATTER SHALL NOT EXCEED THE AMOUNT PAID BY LICENSEE TO BRANDEIS UNDER THIS AGREEMENT. The foregoing exclusions and limitations shall apply to all claims and actions of any kind, whether based on contract, tort (including but not limited to negligence), or any other grounds.

#### 8. DISCLAIMER

BRANDEIS MAKES NO WARRANTY, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR ANY IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE WITH RESPECT TO ANY PATENT, TRADE SECRET, TANGIBLE RESEARCH PROPERTY, TECHNOLOGY, INFORMATION, KNOW-HOW OR DATA LICENSED OR OTHERWISE PROVIDED TO LICENSEE HEREUNDER AND HEREBY DISCLAIMS THE SAME. THE PATENT RIGHTS AND KNOW-HOW ARE PROVIDED AS IS. NOTHING IN THIS AGREEMENT SHALL BE CONSTRUED AS A REPRESENTATION MADE OR WARRANTY GIVEN BY BRANDEIS THAT THE PRACTICE BY LICENSEE OR THE LICENSE GRANTED HEREUNDER SHALL NOT INFRINGE THE PATENT RIGHTS OF ANY THIRD PARTY.

Licensee understands and acknowledges that Brandeis, by this Agreement, makes no representation as to the operability or fitness for any use, safety, efficacy, approvability by regulatory authorities, time and cost of development, patentability, and/or breadth of the Patent Rights, by this Agreement. Brandeis also makes no representation as to whether there are any patents now held, or which will be held, by others or by Brandeis which may be dominant or subordinate to Patent Rights.

#### 9. TERMINATION

- 9.1 Term. Unless sooner terminated as provided for in this Agreement, the license to Patent Rights granted hereunder will be effective upon the Effective Date and will continue on a country by country basis until the first to occur:
  - (a) one (1) year after the date Licensee, its Affiliates, or Sublicensees shall last sell any Licensed Product in such country; or
- (b) until the last to expire of any Patent Right, the claims of which but for this Agreement would be infringed by the manufacture, use or sale of any Licensed Product in the applicable country.

#### 9.2 Termination.

9.2.1 Breach. If Licensee breaches any of its financial obligations under this Agreement, Brandeis may give written notice of the default to Licensee. Unless such default is corrected within thirty (30) days after such notice, Brandeis may immediately terminate this Agreement and the license hereunder without any additional notice. Only one such thirty (30) day grace period shall be available in any twelve (12) month period with respect to a default of any particular financial provision hereunder. Thereafter notice of default of such provision shall constitute immediate termination. If Licensee materially breaches any of its obligations, other than the financial obligations specified above in this paragraph, Brandeis may give written notice of the default to Licensee. Unless such default is corrected within sixty (60) days after such notice, Brandeis may immediately terminate this Agreement and the license hereunder without any additional notice. Only one such sixty (60) day grace period shall be available in any twelve (12) month period with respect to a default of any particular non-financial provision hereunder. Thereafter notice of default of such provision shall constitute immediate termination.

9.2.2 Bankruptcy. Licensee must provide notice to Brandeis of its intention to file a voluntary petition in bankruptcy or, where known to Licensee, of another party's intention to file an involuntary petition in bankruptcy for Licensee, within at least thirty (30) days prior to filing such petition. Brandeis may terminate this Agreement upon receipt of such notice at its sole discretion. Licensee's failure to provide such notice to the University will be deemed a material, pre-petition, incurable breach of this Agreement and the Agreement will terminate automatically on the date of filing such voluntary or involuntary petition in bankruptcy.

## 9.3 Effect of Termination.

- 9.3.1 Sublicenses. Upon any termination, all licenses granted to Licensee and Affiliates under this Agreement are terminated, however, any sublicense under such license granted prior to termination shall remain in full force and effect, provided that:
  - (a) Brandeis receives all payments due hereunder; and
  - (b) the Sublicensee is not then in breach of its sublicense agreement; and
- (c) the Sublicensee assumes in writing Licensees' or the applicable Affiliates' obligations under, and the terms and conditions of this Agreement; and
- (d) Brandeis shall have the right to receive the greater of (a) [\*\*\*] or (b) the lowest royalty which is within the "Competitive" range as hereinafter defined, at the time Brandeis' license to Licensee is terminated. A royalty rate shall be regarded as "Competitive" if it is within the range of royalty rates that [\*\*\*]; and
- (e) Brandeis shall not assume, and shall not be responsible to such Sublicensee for, any representations, warranties or obligations of Licensee to such Sublicensee, other than to permit such Sublicensee to exercise any rights to Patent Rights that are granted under such sublicense agreement consistent with the terms of this Agreement.
- 9.3.2 Obligations. Termination of this Agreement does not relieve Licensee or any Affiliate of any obligation or liability accrued by Licensee or any Affiliate prior to the effective date of such termination or affect any rights of Brandeis arising under this Agreement prior to termination. Also, upon any termination of this Agreement, whether by Brandeis or by Licensee, Licensee and its Affiliates shall cease all use of the Patent Rights and Know-How, and shall, upon request, return or destroy (at Brandeis' option) all tangible embodiments thereof under its control or in its possession.
- 9.4 <u>Survival</u>. In addition to provisions that expressly provide for survival, Sections 1, 4.4, 6, 7, 8, 9.3, 9.4, and 10.5 survive termination of this Agreement.

#### 10. MISCELLANEOUS

10.1 Relationship of the Parties. The parties to this Agreement are independent contractors. It is expressly agreed that in exercising its rights granted hereunder, each party is acting as independent contractor and not as agent or employee of the other party, and nothing contained in this Agreement shall be construed to create an agency, joint venture, or partnership between the parties. Neither party shall have any right, power or authority to enter into any agreement for or on behalf of, or incur any obligation or liability of, or to otherwise bind, the other party.

10.2 Use of Names; Publicity. Except as required by law, neither party shall use the name of the other party or any of their respective officers, employees, students, consultants, Affiliates or agents (or any trade-name, trademark, trade device, service mark, symbol, or any abbreviation, contraction or simulation thereof owned by the other party or any of their respective officers, employees, students, consultants, Affiliates or agents) in any press release, promotional material or other publicity without the prior written consent of the other party.

10.3 Notice. Any notices or other communications required or permitted hereunder shall be sufficiently given if delivered personally, sent by reputable overnight delivery service (such as Federal Express or Airborne Express) or sent by first class certified United States mail, postage prepaid, addressed as follows or to such other address of which the parties may have given notice:

To Brandeis:

Director
Office of Technology Licensing
Brandeis University
415 South Street, MS 115
Waltham, Massachusetts 02454-9110

To Licensee:

c/o Fidelity Biosciences Corp., One Main Street, 13th Floor, Cambridge, MA 02142, Attention: [\*\*\*]

Unless otherwise specified herein, such notices or other communications shall be deemed received (a) on the date delivered, if delivered personally, (b) one business day after being sent, if sent by reputable overnight delivery service or (c) three business days after being sent, if sent by certified mail.

10.4 Assignment. This Agreement may not be assigned or otherwise transferred by Licensee without the prior written consent of Brandeis, such consent not to be unreasonably withheld, delayed or conditioned. Notwithstanding the foregoing, this Agreement may be assigned by Licensee without the consent of Brandeis (a) to an Affiliate, and (b) in connection with the transfer or sale, directly or indirectly, of all or substantially all of the assets and business of Licensee to a third party, whether by merger, sale of stock, sale of all or substantially all assets, consolidation, recapitalization, or other business combination, provided that, with respect to (a) and (b) above, (i) Licensee is in good standing, (ii) any such permitted assignee shall assume all obligations of its assignor under this Agreement in writing, (iii) Licensee or assignee shall deliver a fully executed copy of such assumption of obligations to Brandeis within [\*\*\*] ([\*\*\*]) days of completing the assignment, and (iv) [\*\*\*]. Any purported assignment in violation of this Section shall be null and void.

- 10.5 Governing Law. This Agreement shall be governed by and construed in accordance under the laws of The Commonwealth of Massachusetts, without giving effect to its principles of conflict or choice of laws. Each of the parties hereto agree that any action at law or in equity arising out of or relating to this Agreement shall be filed exclusively in courts of competent jurisdiction located in Boston, Massachusetts. Each party hereby consents to the personal jurisdiction of the courts in The Commonwealth of Massachusetts.
- 10.6 Entire Agreement; Amendments. This Agreement and its Exhibits represent the entire understanding and agreement between the parties hereto with respect to the subject matter hereof and supersede all prior oral and written and all contemporaneous oral negotiations, commitments and understandings between such parties. This Agreement may not be modified or amended except by a written agreement duly executed by both parties hereto.
- 10.7 Waivers. No delay on the part of any party in exercising any right, power or privilege hereunder shall operate as a waiver thereof nor shall any waiver on the part of any party of any such right, power or privilege, nor any single or partial exercise of any such right, power or privilege, preclude any further exercise thereof or the exercise of any other such right, power or privilege. The rights and remedies of any party based upon, arising out of or otherwise in respect of any inaccuracy in or breach of any representation, warranty, covenant or agreement contained in this Agreement shall in no way be limited by the fact that the act, omission, occurrence or other state of facts upon which any claim of any such inaccuracy or breach is based may also be the subject matter of any other representation, warranty, covenant or agreement contained in this Agreement (or in any other agreement between the parties) as to which there is not inaccuracy or breach.
- 10.8 Section Headings. The Section headings are for the convenience of the parties and in no way alter, modify, amend, limit, or restrict the contractual obligations of the parties.
- 10.9 Severability. If any part of this Agreement is ruled to be invalid, illegal, or unenforceable by a court or other body of competent jurisdiction, the remainder of this Agreement shall continue in full force and effect and shall be deemed modified to the minimum extent necessary to make it enforceable. If any such ruling in question is subsequently overruled or obviated by legislative or other action, the severed provisions of this Agreement shall return to full force and effectiveness.
- 10.10 Counterparts. This Agreement may be executed in two or more counterparts, which may be facsimile counterparts, each of which shall be deemed to be an original, but all of which shall be deemed collectively one and the same instrument.
- 10.11 Export Control. Licensee acknowledges and agrees that Brandeis is subject to United States laws and regulations controlling the export of technical data, computer software, laboratory prototypes and other commodities (including the Arms Export Control Act, as amended and the Export Administration Act of 1979), and that its obligations hereunder are contingent on compliance with applicable United States export laws and regulations. The transfer

of certain technical data and commodities may require a license from the cognizant agency of the United States Government and/or written assurances by Licensee that Licensee shall not export data or commodities to certain foreign countries, or to any individuals or entities on the U.S. Treasury Department's List of Specifically Designated Nationals or the U.S. Commerce Department Table of Designated Orders without prior approval of such agency. Brandeis neither represents that a license shall not be required nor that, if required, it shall be issued.

10.12 Marking. Licensee agrees to mark Licensed Products sold in the United States with all applicable United States patent numbers as appropriate. All Licensed Products shipped to or sold in other countries shall be marked in such manner as to conform with the patent laws and practice of the country of manufacture or sale.

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed by their duly authorized officers as of the Effective Date.

BRI-ALZAN INC.		BRANDEIS UNIVERSITY	
By:	/s/ Stacie Weninger	By:	/s/ Irving R Epstein
Name:	Stacie Weninger	Name:	Irving R Epstein, Ph.D.
Title:	President	Title:	Interim Executive Director
			Office of Technology Licensing

#### **EXHIBIT A**

- A.1 <u>Royalty Rate</u>. Beginning with the First Commercial Sale in any country, and on all sales thereafter of Licensed Products anywhere in the world by any Seller, so long as the Patent Rights are in effect, Licensee shall pay Brandeis royalties for each Licensed Product sold by each Seller as follows:
  - (i) [\*\*\*] percent ([\*\*\*]%) of the Net Sales Price of Licensed Products.
- (ii) <u>One Royalty</u>. Only one royalty under Section A.1 shall be due and payable to Brandeis by any Seller for any Licensed Product regardless of the number of Patent Rights covering such Licensed Product.
- A.2 <u>License Maintenance Fees.</u> Licensee shall pay to Brandeis the following license maintenance fees on the dates set forth below. Such license maintenance fees are waived while the Research Agreement is in effect.

	Amount due from	Amount due from
	Licensee prior to Change of	Licensee after Change of
Payment Date	Control	Control
(i) January 1, 2013 and January 1, 2014	\$[***]	\$[***]
(ii) January 1, 2015, and each January 1 thereafter until [***]	\$[***]	\$[***]
(iii) January 1 of each year after [***]	\$[***]	\$[***]

License maintenance fees are nonrefundable; however, the license maintenance fee may be credited to running royalties and sublicense payments subsequently due on Net Sales earned during the same calendar year, if any. License maintenance fees paid in excess of running royalties and sublicense payments due in such calendar year shall not be creditable to amounts due for future years.

A.3 <u>Milestone Payments</u>. Licensee shall pay to Brandeis the following milestone payments due and payable within [\*\*\*] ([\*\*\*]) days of the first occurrence of the following events:

Milestone	Milestone Amount
(i) [***]	<b>\$[***</b> ]
(ii) [***]	\$[***]
(iii) [***]	\$[***]

## A.4 Equity.

(i) Initial Grant. Licensee shall issue a total of one hundred (100) shares of Common Stock of Licensee, \$0.01 par value per share, (the "Shares") in the name of Brandeis. Such issuance shall be recorded on the Stock Transfer Ledger of Licensee on the Effective Date and the Shares shall be delivered to Brandeis within thirty (30) days of the Effective Date.

Company represents to Brandeis that, as of the Effective Date, the aggregate number of Shares equals Five Percent (5%) of the Licensee's issued and outstanding Common Stock calculated on a "Fully Diluted Basis." For purposes of this Section A.4, "Fully Diluted Basis" shall mean that the total number of issued and outstanding shares of the Licensee's Common Stock shall be calculated to include conversion of all issued and outstanding securities then convertible into common stock, the exercise of all then outstanding options and warrants to purchase shares of common stock whether or not then exercisable, and shall assume the issuance or grant of all securities reserved for issuance pursuant to any Licensee stock or stock option plan in effect on the date of the calculation.

## (ii) Anti-Dilution Protection. [\*\*\*].

(iii) <u>Assignment of License Agreement</u>. If Licensee assigns the License Agreement as permitted in Section 10.4, and such assignment does not result in all of Licensee's equity holders exchanging their equity in Licensee for new equity in the assignee, then, at Brandeis' option in its sole discretion, Brandeis shall [\*\*\*]. This provision shall apply to each and every assignee permitted without the prior consent of Brandeis under Section 10.4.

A.5 <u>Sublicense Lump Sum Payments</u>. In addition to the royalties provided for above, Licensee shall pay Brandeis [\*\*\*] percent ([\*\*\*]%) (hereinafter "Lump Sum Percentage") of all lump sum payments received from Sublicensees (hereinafter "Lump Sum Payments"), excluding any payments made specifically for reimbursement of actual research support expenses, and excluding royalties on Net Sales, which are accounted for in Section A. 1, above. Such payments shall be made to Brandeis within [\*\*\*] ([\*\*\*]) days after Licensee receives any Lump Sum Payment from a Sublicensee under any sublicense.

# EXHIBIT B

# Patent Rights

[\*\*\*]

## FIRST AMENDMENT TO LICENSE AGREEMENT

THIS FIRST AMENDMENT TO THE LICENSE AGREEMENT is made effective as of this 31 day of December, 2015 (this "Amendment") by and between Brandeis University, a not- for-profit corporation duly organized and existing under the laws of The Commonwealth of Massachusetts and having its principal place of business at 415 South Street, Waltham, Massachusetts 02454-9110 ("Brandeis"), and BRI-Alzan Inc., a corporation duly organized and existing under the laws of the State of Delaware having its offices at c/o F-Prime Inc., One Main Street, 13th Floor, Cambridge, Massachusetts 02142 (hereinafter referred to as "Licensee"). MeiraGTx Limited, a private limited company duly formed under the laws of England and Wales, joins in this Amendment solely for the limited purposes set forth in Paragraph 2.a.

WHEREAS, Brandeis and Licensee are parties to that certain License Agreement effective as of May 1, 2013 (the "License Agreement");

WHEREAS, Licensee is entering into that certain Agreement and Plan of Merger dated as of the date hereof (the "Merger Agreement") by and among Licensee, MeiraGTx Acquisition Corporation, a Delaware corporation ("Merger Sub"), the stockholders of Licensee comprised of F-Prime Inc. (f/k/a Fidelity Biosciences Corp.) ("Fidelity"), Gregory Petsko, Dagmar Ringe and Brandeis (collectively, the "Sellers"), Fidelity, solely in its capacity as representative of the Sellers, and MeiraGTx Limited, a private limited company duly formed under the laws of England and Wales and the sole stockholder of Merger Sub ("Parent"), pursuant to which Licensee will merge with and into Merger Sub with Licensee surviving the merger and thereby becoming a wholly-owned subsidiary of Parent (the "Merger");

WHEREAS, as part of the consideration for the Merger, Parent will have certain conditional obligations to make the Contingent Payments (as defined in the Merger Agreement), subject to the terms and conditions of (and solely to the extent required by) the Merger Agreement;

WHEREAS, Parent, in connection with the Merger, has requested certain changes to the License Agreement, to which its subsidiary will be a party after the Merger; and

WHEREAS, in connection with the Merger and the acknowledgements herein below set forth in Paragraph 2, Brandeis and Licensee are willing to amend the License Agreement in certain respects as herein set forth.

NOW, THEREFOR, in consideration of the Merger Consideration (as defined in, and subject in all respects to the terms and conditions set forth in, the Merger Agreement) and the mutual promises and agreements herein set forth, Brandeis and Licensee do hereby agree as follows:

1. <u>Definitions</u>. Capitalized terms used, but not otherwise defined in this Amendment, shall have the meanings assigned to such terms under the License Agreement.

## 2. Acknowledgments.

- (a) Parent. Parent hereby acknowledges and agrees that if (i) the License Agreement is assigned after the consummation of the Merger such that another Person, who is not a direct or indirect Affiliate of Parent has assumed Licensee's obligations to Brandeis under the License Agreement (as amended by this Amendment) (each, a "Permitted Transferee"), and (ii) Parent does not also assign its obligations to make the Contingent Payments under the Merger Agreement to such Permitted Transferee or a direct or indirect Affiliate thereof, then (x) Parent's then-remaining obligations under the Merger Agreement to make the Contingent Payments (subject to, and in accordance with, the terms and conditions of the Merger Agreement) shall not be affected by such assignment of the License Agreement. For greater clarity, nothing in this Section 2(a) shall alter the requirements for a valid assignment under Section 7.7 of the Merger Agreement.
- (b) Brandeis. Solely with respect to the transfer of the License Agreement in connection with the Merger, Brandeis agrees to waive application of the higher license maintenance fees for a Change of Control set forth in Section A.2 of Exhibit A of the License Agreement and that the license maintenance fees set forth in column captioned "Amount due from Licensee prior to Change of Control" shall remain in effect immediately following the consummation of the Merger. Neither Parent nor any Person that is an Affiliate of Parent (which shall include the Licensee) shall be bound to issue or otherwise deliver to Brandeis by virtue of the Merger at any time from and after the completion of the Merger any equity other than the Parent Shares allocated to Brandeis on Schedule 2.1.5 to the Merger Agreement. Notwithstanding anything to the contrary in the License Agreement, Brandeis hereby consents to the Merger. Brandeis further acknowledges and agrees that from and after the completion of the Merger, the License Agreement, as amended by this Amendment, shall remain and continue in full force and effect.
- (c) Licensee. Licensee hereby acknowledges and agrees that the consummation of the Merger does not terminate or otherwise alter or affect its obligations to Brandeis under the terms and conditions of the License Agreement, as amended by this Amendment, which shall remain and continue in full force and effect from and after the completion of the Merger.
  - 3. Amendments to License Agreement. Brandeis and Licensee hereby amend the License Agreement as follows:
- (a) The definition of the term "Change of Control" contained in Section 1.4 of the License Agreement is hereby amended to add the following after at the end of the paragraph:
  - A "Change of Control" shall not include a public offering of capital stock of Licensee or of the share capital of Parent or of a holding company of Parent, so long as Parent or such holding company of Parent is an Affiliate of Licensee.
- (b) The definition of the term "Gross Sales" contained in Section 1.7 of the License Agreement is hereby deleted and amended and restated in its entirety as follows:

"Gross Sales" or "Gross Sales Price" means for any arm's length sale, transfer, dispositions or other dealing to a customer by a Seller, the Gross Sales Price shall be the gross amount invoiced by the Seller for the sale, transfer or other disposition of or dealing with a Licensed Product.

Transfer of a Licensed Product within the Licensee or between Licensee, Sublicensee or an Affiliate shall not be considered a sale, commercial use or disposition for the purpose of the foregoing paragraphs; in the case of such transfer the Gross Sales Price shall be based on sale of the Licensed Product by the transferee. If a Seller commercially uses or disposes of any Licensed Product by itself other than in an arm's length sale to a bona fide customer, the Gross Sales Price hereunder shall be the price which would be then payable in an arm's length transaction. [\*\*\*] The "Gross Sales" or "Gross Sales Price" shall not include transfers or dispositions for charitable, compassionate, promotional, pre- clinical, clinical, regulatory, or governmental purposes.

For any sale of a Licensed Product to which the United States government is entitled to a royalty-free right pursuant to 35 USC 202(c)(paragraph 4), [\*\*\*].

- (c) The definition of the term "Net Sales" contained in Section 1.12 of the License Agreement is hereby deleted and amended and restated in its entirety as follows:
  - "Net Sales" or "Net Sales Price" means the Gross Sales Price received by a Seller less (to the extent appropriately documented) the following amounts actually paid out by a Seller or credited against the amounts received by it from the sale or distribution of Licensed Product:
  - (a) credits, allowances and price adjustments for damaged, defective or rejected Licensed Products or for the rejection or return of Licensed Products previously sold;
    - (b) rebates, chargeback payments and trade, cash and quantity discounts to purchasers allowed and taken;
  - (c) amounts for transportation, insurance, handling or shipping charges or directly related to the sale or distribution of Licensed Product and listed on the invoices or purchase order for such Licensed Product;
  - (d) taxes, tariffs, duties and other governmental charges levied on or measured by the sale of Licensed Products, whether absorbed by the Seller or paid by the purchaser so long as the Seller's price is reduced thereby, but not franchise or income taxes of any kind whatsoever;

For Net Sales of a Licensed Product sold or supplied as a Combination Product, the Net Sales of such a Combination Product will be determined, subject to the provisions set forth below in this Section 1.12, by multiplying the actual Net Sales of such Combination Product in a particular country in the Territory by the fraction of A/(A+B), where A is the average Gross Sales billed or invoiced per unit of such Licensed Product in such country in the Territory during the period in respect of which Net Sales are being calculated of the Licensed Product sold separately and B is the total average Gross Sales billed or invoiced per unit in such country in the Territory of the other active ingredient (including a biologic product) or device included in the Combination Product during the period in respect of which Net Sales are being calculated, when sold separately. If neither the Licensed Product nor the other active ingredient (including a biologic product) or device included in the Combination Product are sold separately as a monotherapy during the period in respect of which Net Sales are being calculated, then the fair market value of the other active ingredient (including a biologic product) or device included in the Combination Product that is to be deducted from the Net Sales of the Combination Product in determining the Net Sales of the Licensed Product contained in the Combination Product shall be equal to the fair market value of such other active ingredient (including a biologic product) or device included in the Combination Product as determined in accordance with the provisions of the Merger Agreement for such Licensed Product. As used herein, a "Combination Product" means a product which comprises (a) a Product and (b) at least one other active ingredient (including a biologic product) or medical device."

Subject to the above, Net Sales shall be calculated in accordance with United Kingdom generally accepted accounting principles (or U.K. GAAP), consistently applied with the past practice of the Licensee and its Affiliates."

- (d) Exhibit A to the License Agreement is hereby deleted in its entirety and amended, restated and replaced in its entirety with Exhibit A attached to this Amendment. On and after the Effective Date of this Amendment, each reference to Exhibit A in the License Agreement shall mean and be a reference to Exhibit A attached to this Amendment.
- (e) Exhibit B to the License Agreement is hereby deleted in its entirety and amended, restated and replaced in its entirety with Exhibit B attached to this Amendment. On and after the Effective Date of this Amendment, each reference to Exhibit B in the License Agreement shall mean and be a reference to Exhibit B attached to this Amendment.

- (f) Section 3.1(a) of the License Agreement is hereby amended to delete the phrase "During the last [\*\*\*] ([\*\*\*]) months of the Research Agreement Term," and to substitute the following phrase: "On or prior to June 30, 2016,"
  - (g) Section 3.3 of the License Agreement is hereby amended to add the following after at the end of the paragraph:

As of the Effective Date of this Amendment, it is understood that Licensee does not have any obligations, financial or otherwise, under the Research Agreement.

(h) The address for notice for Licensee set forth in Section 10.3 of the License Agreement is amended as follows:

"To Licensee: c/o MeiraGTx Limited 450 East 29th Street, 5th Floor New York, New York 10016 Attn: [\*\*\*]"

(i) The second sentence of Section 10.4 of the License Agreement is hereby deleted and amended and restated in its entirety as follows:

"Notwithstanding the foregoing, this Agreement may be assigned by Licensee without the consent of Brandeis (a) to an Affiliate, and (b) in connection with the transfer or sale, directly or indirectly, of all or substantially all of the assets and business of Licensee to a third party, whether by merger, sale of stock, sale of all or substantially all assets, consolidation, recapitalization, or other business combination, provided that, with respect to (a) and (b) above, (i) Licensee is in good standing under the laws of its jurisdiction of incorporation or formation, (ii) any such permitted assignee (1) has total net assets (total assets minus total liabilities) reflected on its balance sheet as of the end of the then most recently completed fiscal year that are equal to or greater than Licensee's total net assets as reflected on a balance sheet as of the end of Licensee's then most recently completed fiscal year, (2) (A) is not the subject of any litigation or proceeding (including, but not limited to arbitration), in law or in equity, and (B) there are no proceedings or known governmental investigations before any administrative or governmental authority (including any commission), pending or threatened against such permitted assignee, in each case with respect to clauses (A) and (B), that would reasonably be expected to impair its ability to fulfill its obligations under the License Agreement, and (3) shall assume all obligations of its assignor under this Agreement in writing, and (iii) Licensee or assignees shall deliver a fully executed copy of such assumption of obligations to Brandeis within [\*\*\*] ([\*\*\*\*]) days of completing the assignment. For purposes of this Section 10.4, "known" shall mean "known by such permitted assignee."

- 4. <u>Representations</u>. Brandeis hereby represents and warrants to the Licensee, and Licensee hereby represents and warrants to Brandeis, that this Amendment has been duly authorized and executed and delivered by such party and is a legal, valid, binding and enforceable obligation of such party, except as such enforceability may be limited by bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' rights generally and by general principles of equity.
- 5. No Implied Amendments . Except as herein provided, the License Agreement shall remain in full force and effect and are ratified in all respects. On and after the Effective Date of this Amendment, each reference in the License Agreement to "this Agreement," "hereunder," "herein," or words of like import, and each reference to the License Agreement in any other agreements, documents or instruments executed and delivered from and after the Effective Date of this Amendment, shall mean and be a reference to the License Agreement, as amended by this Amendment.
- 6. <u>Governing Law</u>. This Amendment shall be construed in accordance with the laws of the Commonwealth of Massachusetts, without regard to the choice of laws rules thereof, and the obligations, rights and remedies of the parties hereunder shall be determined in accordance with such laws. Any legal suit, action or proceeding against any of the parties hereto arising out of or relating to this Amendment shall only be instituted in any federal or state court located in Boston, Massachusetts, and each party hereby irrevocably submits to the exclusive jurisdiction of any such court in any such suit, action or proceeding. The parties hereby agree to venue in such courts and hereby waive, to the fullest extent permitted by law, any claim that any such action or proceeding was brought in an inconvenient forum. Each of the parties hereby irrevocably waives all right to trial by jury in any action, proceeding or counterclaim arising out of or relating to this Amendment.
- 7. Entire Agreement and the Merger Agreement constitute the entire agreement among the parties with respect to the subject matter hereof and supersede all prior agreements, understandings and undertakings, both written and oral, among the parties, or any of them, with respect to the subject matter hereof.
- 8. <u>Counterparts</u> .. This Amendment may be executed in several counterparts, each of which will be deemed an original but all of which will constitute one and the same.
- 9. <u>Effective Date</u>. For the avoidance of doubt, this Amendment shall be effective upon the completion of the Merger pursuant to the Merger Agreement as evidenced by the filing by Licensee of a certificate of merger with the Secretary of State of the State of Delaware.

[ Remainder of page intentionally left blank. ]

IN WITNESS WHEREOF, the parties have caused this Amendment to be executed by their duly authorized officers as of the Effective Date.

WITNESS/ASSEST:		BRANDEIS UNIVERSITY		
By:	/s/ Diane P. Walsh	By:	/s/ Rebecca Menapace	
Name:	Diane P. Walsh	Name:	Rebecca Menapace	
Title:	Dept. Coordinator, OTL	Title:	Associate Provost for Innovation	
	Brandeis University	_	Executive Director, OTL	
		BRI-ALZAN	N INC.	
By:	/s/ Allan S. Galper	By:	/s/ Stacie Weninger Barnes	
Name:	Allan S. Galper	Name:	Stacie Weninger Barnes	
Title:	Secretary	Title:	President	
		For the limit	For the limited purposes set forth in Paragrah 2.a. of this Amendment:	
		MEIRAGTx LIMITED		
By:	/s/ Richard Giroux	By:	/s/ Zandy Forbes	
Name:	Richard Giroux	Name:	Zandy Forbes	
Title:	COO	Title:	CEO	

## **EXHIBIT A**

A.l <u>Royalty Rate</u>. Beginning with the First Commercial Sale in any country, and on all sales thereafter of Licensed Products anywhere in the world by any Seller, so long as the Patent Rights are in effect, Licensee shall pay Brandeis royalties for each Licensed Product sold by each Seller as follows:

- (i) [\*\*\*] percent ([\*\*\*]%) of the Net Sales Price of Licensed Products.
- (ii) <u>One Royalty</u>. Only one royalty under Section A.l shall be due and payable to Brandeis by any Seller for any Licensed Product regardless of the number of Patent Rights covering such Licensed Product.
- A.2 License Maintenance Fees. Licensee shall pay to Brandeis the following license maintenance fees on the dates set forth below.

	Amount due from Licensee	Amount due from Licensee
Payment Date	prior to Change of Control	after Change of Control
(i) January 1, 2016, and each January 1 thereafter until [***]	\$[***]	\$[***]
(ii) January 1 of each year after [***]	\$[***]	\$[***]

License maintenance fees are nonrefundable; however, the license maintenance fee may be credited to running royalties and sublicense payments subsequently due on Net Sales earned during the same calendar year, if any. License maintenance fees paid in excess of running royalties and sublicense payments due in such calendar year shall not be creditable to amounts due for future years.

A.3 <u>Milestone Payments</u>. Licensee shall pay to Brandeis the following milestone payments due and payable within [\*\*\*] ([\*\*\*]) days of the first occurrence of the following events:

Milestone	Milestone Amount
(i) [***]	\$[***]
(ii) [***]	\$[***]
(iii) [***]	\$[***]

A.4 <u>Sublicense Lump Sum Payments</u>. In addition to the royalties provided for above, Licensee shall pay Brandeis [\*\*\*] percent ([\*\*\*]%) (hereinafter "Lump Sum Percentage") of all lump sum payments received from Sublicensees (hereinafter "Lump Sum Payments"), excluding any payments made specifically for reimbursement of actual research support expenses, and excluding royalties on Net Sales, which are accounted for in Section A.l, above. Such payments shall be made to Brandeis within [\*\*\*] ([\*\*\*]) days after Licensee receives any Lump Sum Payment from a Sublicensee under any sublicense.

# **EXHIBIT B**

[\*\*\*]

## LICENCE AGREEMENT

between

## **UCL Business Plc**

and

## Athena Vision Ltd

## Dated 4 February 2015

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## THIS AGREEMENT is made

#### BETWEEN:

- (1) **UCL BUSINESS PLC**, whose registered office is The Network Building, 97 Tottenham Court Road, London W1T 4TP ("UCLB");
- (2) **ATHENA VISION LTD**, a company incorporated in England and Wales under company registration number 09348737 whose principal place of business is at c/o UCL Business PLC, The Network Building, 97 Tottenham Court Road, London W1T 4TP United Kingdom (the "Licensee").

## WHEREAS:

- A. University College London ("UCL") has developed certain ocular gene therapies and owns certain Intellectual Property relating to those gene therapies that the Licensee wishes to acquire rights to for the development and commercialisation of Licensed Products.
- B. UCL has assigned, or will assign prior to the execution of the relevant Licence Addendum, to UCLB all of its right, title and interest in and to such Intellectual Property.
- C. The parties have agreed to enter into this multiple licence agreement to govern the terms upon which, following the execution of a Licence Addendum, such Intellectual Property may be licensed to the Licensee.
- D. It is the policy of UCLB that its activities in licensing intellectual property take into consideration ethical and socially responsible licensing principles, including ensuring that Licensed Products are made available to fulfil unmet needs in Developing Countries, and the Licensee acknowledges and agrees to carry out its activities under this Agreement in a manner which complies with ethical and socially responsible licensing principles and which is designed to fulfil such needs, all in accordance with the provisions of this Agreement.

# NOW IT IS AGREED as follows:

## 1. **DEFINITIONS**

1.1 In this Agreement:

**Agreement** means this agreement (including the Schedules) and unless otherwise specified or the context otherwise requires, all Licence Addendums in respect of Licensed Technologies entered into between the parties hereunder;

Affiliate in relation to a Party, means any entity or person that Controls, is Controlled by, or is under common Control with that Party;

**At-Cost Markets** means those markets in Developing Countries [\*\*\*];

Claims means all demands, claims and liability (whether criminal or civil, in contract, tort or otherwise) for losses, damages, costs and expenses of any nature whatsoever and all costs and expenses (including legal costs) incurred in connection therewith;

**Commencement Date** means 4 February 2015;

**Commercial Third Party** means a commercial entity that is not a Party of this Agreement;

**Competing Product** means any product, whether ready for marketing or in development that competes, or is likely to compete once developed, with any Licensed Product;

**Confidential Information** means the Know-how and all other technical or commercial information that:

- a) in respect of information provided in documentary form or by way of a model or in other tangible form, at the time of provision is marked or otherwise designated to show expressly that it is imparted in confidence or which a reasonable person would expect to be confidential; and
- b) in respect of information that is imparted orally, any information that the Disclosing Party or its representatives informed the Receiving Party at the time of disclosure or which a reasonable person would expect to be confidential;

**Control** means direct or indirect beneficial ownership of 50% (or, outside a Party's home territory, such lesser percentage as is the maximum permitted level of foreign investment) or more of the share capital, stock or other participating interest carrying the right to vote or to distribution of profits of that Party, as the case may be;

**Cost-Based Price** means, in respect of each Licensed Product, [\*\*\*];

**CPI** means the United Kingdom Consumer Prices Index as published by the UK Office for National Statistics (or any successor body) or, if that index ceases to exist or the basis of the index is fundamentally changed, the nearest equivalent UK official index of increases in consumer prices as agreed by the Parties or in the absence of agreement determined by an expert appointed in accordance with Clause 5.10;

**Developing Country** or **Developing Countries** refers to those countries that are:

- a) [\*\*\*]; and
- b) to the extent not included in a);
  - i) defined as of the Commencement Date [\*\*\*]; and
  - ii) all other countries that may be mutually agreed to by the University and Licensee from time to time;

**Developing Country Manufacturer** means a manufacturer of pharmaceutical products that is able to efficiently manufacture (either within or outside the Developing Country in which the At-Cost market exists), distribute and supply the Licensed Product in an At-Cost market at a Cost-Based Price;

**Diligent Efforts** means exerting such efforts and employing such resources as would normally be exerted or employed by [\*\*\*], when utilizing sound and reasonable scientific, medical and business practice and judgment in order to develop the product in a timely manner and generate an economic return to the Parties from its commercialisation;

**Disclosing Party** has the meaning given in Clause 3.3;

**Field** means ocular gene therapy;

**Founders** means [\*\*\*];

**Indemnitees** has the meaning given in Clause 10.6;

**Intellectual Property** means any and all patents, utility models, registered designs, unregistered design rights, copyright, database rights, rights in respect of confidential information, rights under data exclusivity laws, rights under orphan drug laws, rights under unfair competition laws, property rights in biological or chemical materials, extension of the terms of any such rights (including supplementary protection certificates), applications for and the right to apply any of the foregoing registered property and rights, and similar or analogous rights in any part of the Territory;

**Know-how** means in respect of each Licensed Technology:

- a) the inventions claimed in the relevant Patents;
- b) the technical information relating to the inventions claimed in the relevant Patents; and
- c) the know how and the Know-how Data (as defined in the relevant Licence Addendum) described in Appendix 1 to the relevant Licence Addendum;

**Licence Addendum** means an addendum in the form set out in Schedule 1, duly signed and executed by the authorised representatives of each of the Parties and annexed to this Agreement;

**Licensed Products** means in respect of each Licensed Technology, any and all products that are developed, manufactured, used, or sold by or on behalf of the Licensee or its Affiliates or Sub-licensees and which (a) are within (or are manufactured using a process described in) a Valid Claim of the relevant Patents and/or (b) incorporate, or their development or manufacture makes use of, any of the relevant Know-how;

**Licensed Technology** means Intellectual Property, Patents and Know how relating to each technology licensed by UCLB to the Licensee under Licensee Addendums [\*\*\*] to this Agreement;

**Materials**, with respect to each Licensed Technology, means any materials, documents and information that UCLB may provide to the Licensee under or in connection with this Agreement;

**Net Receipts** means in respect of the Licensed Products, [\*\*\*];

**Net Sales Value** means in respect of the [\*\*\*];

Parties means UCLB and the Licensee, and "Party" shall mean either of them;

**Patents** means in respect of the Licensed Technology, any and all of the patents and patent applications described in Appendix 1 to the relevant Licence Addendum including any continuations, continuations in part, extensions, reissues, divisions, and any patents, supplementary protection certificates and similar rights that are based on or derive priority from the foregoing;

**Reasonable Developing Country Licence Terms** means terms that meet the requirements of both UCL's ethical and socially responsible licensing policy, which is at: (<a href="http://www.ucl.ac.uk/enterprise/about/policies/files/Global\_access-final.pdf">http://www.ucl.ac.uk/enterprise/about/policies/files/Global\_access-final.pdf</a>) and the following principles:

- a) the Licensee shall [\*\*\*];
- b) the Developing Country licence terms [\*\*\*] that shall not [\*\*\*];
- c) if the Developing Country Manufacturer is granted any exclusive rights, the continued grant of those rights shall be conditional upon the Developing Country Manufacturer supplying At-Cost Markets at a Cost-Based Price and meeting market demand in that market; and
- d) the Licensee may impose reasonable conditions, including as to use of trade marks, trade dress, format and pack size, to differentiate the Licensed Product when sold in the At-Cost market from Licensed Products sold in other markets and to prohibit their export into other markets and territories, provided that such conditions or their implementation do not act as an unreasonable barrier to the prompt and efficient supply of Licensed Product in the At-Cost market;

**Receiving Party** means has the meaning given in Clause 3.3;

**Regulatory Exclusivity** means, with respect to a Licensed Product, any exclusive rights or protection which are recognised, afforded or granted by any Regulatory Authority in any country or region with respect to the Licensed Product other than through patent rights;

**Shareholders' Agreement** means the shareholders' agreement dated on or around the date of this Agreement between UCLB, the Licensee, the Founders and the Manager (as identified therein);

Specified Technology means any and all Intellectual Property owned by UCLB or its Affiliates relating to the following technologies:

[\*\*\*

where subject to Clause 2.4 such Intellectual Property is free from any ownership or other obligations of third parties when it arises or where any such ownership or other obligations to third parties which might exist when it arises have been discharged or waived;

**Sub-licensee** means in respect of each Licensed Technology, any third party (other than an Affiliate) to whom the Licensee grants a sub-licence of its rights under this Agreement in accordance with Clause 2.3;

Territory means Worldwide; and

**Valid Claim** means a claim of a patent or patent application that has not been abandoned or allowed to lapse or expired or been held invalid or unenforceable by a court of competent jurisdiction in a final and non-appealable judgment.

## 2. GRANT OF RIGHTS

## 2.1 Licence of Licensed Technology

UCLB hereby grants to the Licensee and its Affiliates, and the Licensee hereby accepts on its own behalf and on behalf of its Affiliates, in respect of the Licensed Technology from the effective date specified in the respective Licence Addendums and subject to the provisions of this Agreement, an exclusive licence to use and exploit the Licensed Technology, with the right to sub-license, (subject to Clause 2.3), to develop, manufacture, have manufactured, use, sell and have sold Licensed Products solely in the relevant Field and in the relevant Territory. The licence shall be exclusive even as to UCL subject to Clause 2.4.

2.2 UCLB shall at the Licensee's request and cost execute such formal licences as may be necessary to enable the Licensee to register the licences granted to it under this Agreement with the Patent Offices in the relevant Territory. Such formal licence will reflect the terms of this Agreement where possible and for the avoidance of doubt if there is a conflict in the terms of such formal licence and this Agreement, the terms of this Agreement shall prevail. [\*\*\*].

## 2.3 Sub-Licensing of Licensed Technology

The Licensee shall have the right to grant sub-licences under the licence in Clause 2.1 to its Affiliates or other third parties through one or more levels of Sub-licensees except that the Licensee may not grant such a sub-licence to any person or the Affiliates of any person

involved in: the tobacco industry (as defined by the Cancer Research UK Code of Practice on Tobacco Industry Funding to Universities detailed in Schedule 3); Arms dealing; gambling operations; the promotion of violence; child labour or any other illegal activity. A grant of any sub-licence shall be conditional on the following:

- (a) The Licensee shall enter into a written agreement with each Sub-licensee and shall ensure that the provisions of each sub-licence are consistent with the provisions of this Agreement, and the Licensee shall ensure that:
  - (i) the sub-licence sets out all the proposed terms agreed between the Licensee and the Sub-licensee, including, in particular, all terms as to remuneration;
  - (ii) the Sub-licensee will maintain complete and accurate records in sufficient detail to permit UCLB to confirm the accuracy of the calculation of royalty payments under this Agreement; and
  - (iii) the sub-licence imposes obligations of confidentiality on the Sub-licensee which are no less onerous than those set out in Clause 3.3.
- (b) The Licensee shall procure that each Sub-licensee complies fully at all times with the provisions of its sub-licence.
- (c) The Licensee shall be liable for all acts and omissions of its Sub-licensees that, if committed by the Licensee, would constitute a breach of any of the provisions of this Agreement.
- (d) The Licensee shall provide UCLB with a copy of any sub-licence [\*\*\*] ([\*\*\*]) days after execution of such sub-licence, provided that the Licensee may redact confidential or proprietary terms from such copy, including financial terms.
- (e) Each sub-licence shall terminate automatically upon termination of the relevant Licence Addendum for any reason (other than in the case of expiry of the relevant Licence Addendum under Clause 11.2) except where:
  - (i) the Sub-licensee was not implicated in or at fault in any circumstances which led to the termination; and
  - (ii) the benefit (but not the burden) of the sub-licence agreement is validly assigned to UCLB in writing within [\*\*\*] ([\*\*\*]) days following the date of termination; and
  - (iii) the Sub-licensee agrees that, following assignment, the Sub-licensee will observe in full the terms of the sub-licence agreement including paying all sums due to the Licensee under the sub-licence agreement directly to UCLB in a timely manner,

in which case the Sub-licensee's rights to use the relevant Licensed Technology shall continue in full force and effect in accordance with the terms of the relevant sub-licence agreement.

## 2.4 Reservation of Rights

- 2.4.1 UCLB reserves for itself and UCL the non-exclusive, irrevocable, worldwide, royalty-free right to:
  - (a) Use the Licensed Technology in the Field for academic research, publication and teaching; and
  - (b) Grant licences to academic third parties to use the Licensed Technology in academic research collaborations with UCL; and
  - (c) Grant licences of the Licensed Technology to post graduate students of UCL for the purpose of conducting a programme of post graduate academic research.

In exercising the rights described in Clause 2.4.1(b) and (c), UCL and UCLB shall comply with the provisions of Clause 3 as regards confidentiality of the Know-how.

- 2.4.2 Except for the licences expressly granted by this Clause 2, UCLB grants no rights to the Licensee (whether under this Agreement or the relevant Licence Addendum) to or under any intellectual property other than the Licensed Technology and hereby reserves all rights under the Licensed Technology outside the Field.
- 2.4.3 Nothing in this Agreement or any Licence Addendum shall limit or otherwise affect UCL's ability to apply for non-commercial grant funding or comply with such grant terms and conditions. In the event that any terms of this Agreement or any Licence Addendum conflicts with the terms of any non-commercial grant funding, the Parties shall negotiate in good faith to amend the terms of this Agreement or the relevant Licence Addendum to allow UCL to access such funding provided that nothing herein shall require the Licensee to agree to alter or modify the scope of the licence granted to it in this Clause 2.

## 2.5 Affiliates

The Licensee shall:

- 2.5.1 ensure that its Affiliates comply fully with the terms of this Agreement;
- 2.5.2 be responsible for any breach of or non-compliance with this Agreement by its Affiliates as if the breach or non-compliance had been a breach or non-compliance by the Licensee;
- 2.5.3 indemnify in accordance with Clause 10.6 each of the Indemnitees against any Claims which are awarded against or suffered by any of the Indemnitees as a result of any breach of or non-compliance with this Agreement by its Affiliates; and
- 2.5.4 ensure that if any Affiliate ceases to be an Affiliate as a result of a change of Control or otherwise, that unless a sub-licence agreement in accordance with Clause 2.3 is entered into with such an Affiliate, such former Affiliate immediately upon such cessation:

- (a) ceases developing, manufacturing, having manufactured, using, selling and/ or having sold Licensed Products and ceases all use or exploitation of the Licensed Technologies, for as long as any of the relevant Patents remains in force and/or the Know-how remains confidential;
- (b) returns to the Licensee or destroys any documents or other materials in the former Affiliate's possession or under its control and that contain Confidential Information provided under this Agreement relating to the Licensed Technologies and/ or Licensed Products;
- (c) to the extent possible, takes all action necessary to have any product licences, marketing authorisations, pricing and/ or reimbursement approvals (and any applications for any of the foregoing) which relate to Licensed Products transferred into the name of the Licensee.

## 2.6 Option to License Specified Technology

- 2.6.1 UCLB, where it is free and reasonably able to do so, shall grant to the Licensee an exclusive option to negotiate for a royalty-bearing licence to the Specified Technology on reasonable commercial terms to be negotiated in good faith between the Parties (the "Specified Technology Option").
- 2.6.2 The Specified Technology Option in respect of each Specified Technology will be valid and exercisable for a period of 4 years from the Commencement Date (the "Specified Technology Option Period"). If the Licensee wishes to exercise the Specified Technology Option within the Specified Technology Option Period, the Licensee shall serve notice upon UCLB to this effect (the "Specified Technology Option Notice"). UCLB and the Licensee will have a period of up to [\*\*\*] ([\*\*\*]) months from the Licensee's receipt of the Specified Technology Option Notice to negotiate in good faith the commercially reasonable terms of a separate licence agreement governing such licence (the "Specified Technology Negotiation Period"). The Specified Technology Negotiation Period may be extended by mutual agreement of the Parties. If, with respect to any such Specified Technology, either the Licensee does not exercise its Specified Technology Option within the Specified Technology Option Period, or the Licensee and UCLB are unable to agree on the terms of a licence agreement within the Specified Technology Negotiation Period, the Licensee's rights with respective to such Specified Technology pursuant to this Clause 2.6 shall terminate forthwith.

# 3. KNOW-HOW AND CONFIDENTIAL INFORMATION

### 3.1 **Provision of Know-how**

- (a) Within [\*\*\*] ([\*\*\*]) days following the effective date of each Licence Addendum, UCLB shall deliver to the Licensee an outline of the Know-how relating to that Licence Addendum and (where applicable) a list of relevant documents.
- (b) For the avoidance of doubt, UCLB's obligations under this Clause 3.1 shall not extend to any Materials. Materials may be provided to the Licensee as the Parties may agree on a case by case basis. Where Materials are provided to the Licensee, they shall be deemed to be Know-how under this Agreement.

## 3.2 Confidentiality of Know-how

The Licensee undertakes that for so long as the Know-how remains confidential, it shall (and shall ensure that its Affiliates and Sub-licensees) take all reasonable precautions to prevent unauthorised access to the Know-how and protect the Know-how in the same manner as it (or they) protect(s) its (or their) own proprietary information, and shall not (and shall ensure that its Affiliates and Sub-licensees do not) use the Know-how for any purpose, except as expressly licensed hereby and in accordance with the provisions of this Agreement. For the avoidance of doubt, to the extent that any Know-how or information relating to the Licensed Technology falls within the public domain (without any breach of this Agreement or any other obligation of confidentiality), then UCL, the Founders and UCLB shall be free to use such information without restriction in the same way that any third party would have the freedom to use it.

# 3.3 Confidentiality Obligations

Each Party ("Receiving Party") undertakes:

- 3.3.1 to maintain as secret and confidential all Confidential Information obtained from the other Party ("Disclosing Party") in the course of or in anticipation of this Agreement and to respect the Disclosing Party's rights therein;
- 3.3.2 to use such Confidential Information only for the purposes of or as permitted by this Agreement; and
- 3.3.3 to disclose such Confidential Information only to those of its employees, contractors, Affiliates, and Sub-licensees (if any) to whom and to the extent that such disclosure is reasonably necessary for the purposes of this Agreement, provided however that the Licensee shall have the right to disclose Confidential Information received from UCLB to (i) potential or actual customers of Licensed Products and/ or Licensed Services to the extent reasonably necessary to promote the sale or use of Licensed Products and/ or Licensed Services and provided that the customer has agreed to confidentiality provisions at least as restrictive as set forth herein.(ii) to existing potential investors or lenders provided that such third parties have agreed to confidentiality provisions at least as restrictive as set forth herein, and, (iii) to its Board of Directors (or similar governing body) and its counsel, accountants and other professional advisers.

## 3.4 Exceptions to Obligations

The provisions of Clause 3.3 shall not apply to Confidential Information which the Receiving Party can demonstrate by reasonable written evidence:

- 3.4.1 was, prior to the Commencement Date, in the possession of the Receiving Party and at its free disposal and was not obtained or otherwise acquired directly or indirectly from the Disclosing Party or its Affiliates or their respective employees, students or representatives; or
- 3.4.2 is subsequently disclosed to the Receiving Party without any obligations of confidence by a third party; or
- 3.4.3 is or becomes generally available to the public through no act or default of the Receiving Party or its agents, employees, Affiliates or Sub-licensees; or
- 3.4.4 the Receiving Party is required to disclose by or to the courts of any competent jurisdiction, or to any government regulatory agency or financial authority, provided that the Receiving Party shall:
  - (a) inform the Disclosing Party as soon as is reasonably practicable;
  - (b) at the Disclosing Party's request and cost seek to persuade the court, agency or authority to have the information treated in a confidential manner, where this is possible under the court, agency or authority's procedures; and
  - (c) where the disclosure is unavoidable, limit the disclosure of Confidential information to the minimum extent required by law; or
- 3.4.5 which a Party is advised by its information officer that it is required to disclose under the Freedom of Information Act 2000 or the Environmental Information Regulations 2004.

### 3.5 **Disclosure to Employees**

The Receiving Party shall inform all of its employees, contractors, Affiliates and Sub-licensees who have access to any of the Disclosing Party's Confidential Information to which Clause 3.3 applies, shall make all such employees, contractors, Affiliates and Sub-licensees aware of the obligations of confidence and ensure that all recipients of Confidential Information are bound by obligations of confidence no less onerous than those provided for herein (which it undertakes to enforce and for which it is legally responsible) to those of its subsidiaries, employees, and officers as need to have access thereto wholly necessarily and exclusively for the purposes of this Agreement.

## 4. CONFLICT OF INTEREST

The Founders, as employees of UCL and founders of Newco, agree to adhere to UCL's conflict of interest policy: (http://www.ucl.ac.uk/finance/finance\_docs/doi\_policy.html).

## 5. **CONSIDERATION**

### **Equity in Athena Vision Ltd**

- 5.1 On or before the Commencement Date, the Licensee shall provide consideration to UCLB in return for the licensee and other rights granted by UCLB to the Licensee under this Agreement by issuing shares in the share capital of the Licensee in accordance with the Shareholders' Agreement, the Licensee shall:
  - 5.1.1 deliver to UCLB a share certificate in respect of the requisite number of validly issued, fully paid up, ordinary shares in the share capital of the Licensee pursuant to the Shareholders' Agreement, such share certificate to be issued in the name of UCL Business PLC;
  - 5.1.2 ensure that all necessary resolutions have been passed, and its register of members has been written up, to reflect the issue of shares to UCLB referred to in Clause 5.1.1; and
  - 5.1.3 ensure that the appropriate documents and forms shall be filed with the registrar of companies within the time limits prescribed by statute.
- 5.2 For so long as UCLB holds the necessary percentage of the entire issued share capital of the Licensee as required by the Shareholders' Agreement, the Licensee shall ensure that:
  - 5.2.1 UCLB shall at all times be entitled (but not bound) to appoint such person as UCLB may from time to time nominate as a director ("UCLB Director") of the board of directors of the Licensee (the "Board"). The UCLB Director shall have the right to attend (either in person or by any electronic means) and speak at all meetings of the Board and of any committee(s) constituted by the Board, and shall have the right to vote at any such meetings in accordance with the Shareholders' Agreement for NewCo. UCLB shall at all times have the right to vote at any such meetings in accordance with the Shareholders' Agreement for NewCo. UCLB shall at all times have the right to remove any UCLB Director and upon his/her removal, to appoint another UCLB Director in his/her place as and when UCLB deems appropriate in its sole and absolute discretion.
  - 5.2.2 At the same time any notice is sent to any director of the Licensee convening a meeting of the Board or any committee constituted by the Board, such notice shall be sent to the relevant UCLB Director together with a written agenda specifying the matters to be raised at the meeting and copies of all documents to be laid before or discussed at the meeting.

5.2.3 Each UCLB Director shall be at liberty from time to time to make full disclosure to UCLB and its Affiliates of any and all commercial and/or financial information relating to the Licensee. In addition, UCLB and its Affiliates shall be entitled to have prompt and unrestricted access to (i) all trading records and information relating to the operations of the Licensee; (ii) all accounts (including management accounts), books, bank statements, and other financial records of the Licensee; and (iii) all information available to the Licensee concerning any legal or arbitration proceedings threated or commenced against or by the Licensee.

### 5.3 Other Milestone Payments

Within [\*\*\*] ([\*\*\*]) days following achievement of each of the following milestone events, the Licensee shall notify UCLB in writing that the relevant milestone event has been achieved, provide documentary evidence of such achievement as appropriate and pay to UCLB, within a period of [\*\*\*] days, the amount(s) set out next to such milestone event below:

Milestone Event	Amount to be paid
[***]	£[***]
[***]	£[***]

## 5.4 Annual Management Fees

On each date referred to in the following table, the Licensee shall pay to UCLB the annual management fee set out next to such date in the table.

Date	Amount to be paid
Upon each anniversary of the Commencement Date until [*	**] £50,000

If the Licensee fails to pay any such amount by such date, UCLB may in its sole and absolute discretion either (a) convert the licence granted under Clause 2.1 into a non-exclusive licence or (b) elect to treat such non-payment as a material breach of contract under Clause 11.3.1.

## 5.5 Sales Linked Milestone Payments

Upon achievement of each of the sales linked milestones set out in the following table, the Licensee shall notify UCLB in writing that the relevant sales linked milestone has been achieved, provide the relevant documentary evidence and pay to UCLB the amount(s) set out next to such event in the table:

Sales Linked Milestones	Amount to be paid
When Net Sales Value reaches £[***]	£[***]
On the next £[***] of Net Sales Value (when sales cumulatively reach £	
[***])	£[***]
On the next £[***] of Net Sales Value (When sales cumulatively reach £	
[***])	£[***]
On the next £[***] of Net Sales Value (when sales cumulatively reach £	
[***])	£[***]
On the next $\mathfrak{L}[***]$ of Net Sales Value (when sales cumulatively reach $\mathfrak{L}$	
[***])	£[***]
On the next $\mathfrak{L}[***]$ of Net Sales Value (when sales cumulatively reach $\mathfrak{L}$	
[***])	£[***]

### 5.6 Royalties on Net Sales

For each Licensed Technology the Licensee shall pay to UCLB a royalty of [\*\*\*]% ([\*\*\*] per cent) being a percentage of the Net Sales Value of all Licensed Products or any part thereof.

## 5.7 Royalties on Net Receipts

For each Licensed Technology the Licensee shall pay to UCLB a royalty of [\*\*\*] ([\*\*\*] per cent) being a percentage of Net Receipts

5.8 [\*\*\*]

### 5.9 **Combination Products**

If any Licensed Products are incorporated in any other product ("Combination Product") sold by the Licensee or its Affiliates and the Licensed Product is not priced separately from the Combination Product, the Net Sales Value of such Licensed Product shall be deemed to be the fair market value of the Licensed Product in the country of sale when sold separately or if not sold separately in the country of sale, in comparable countries and territories or if neither of the foregoing apply, a reasonable amount which fairly reflects the value of the Licensed Product within the Combination Product assuming the Licensed Product is not being sold as a loss leader.

5.10 [\*\*\*]

### 5.11 **Payment Frequency**

Royalties due under this Agreement, except for Management Fees, Other Milestone payments and Sales Milestone payments, which are payable upon the date specified in Clauses 5.3, 5.4 and 5.5 as appropriate, shall be paid within [\*\*\*] ([\*\*\*]) days following the end of each calendar quarter ending on 31 March, 30 June, 30 September and 31 December in each year, in respect of sales of Licensed Products made and Net Receipts generated during such quarter and within [\*\*\*] ([\*\*\*]) days following the termination of the relevant Licence Addendum.

### 5.12 Payment terms

All sums due under this Agreement:

- 5.12.1 are exclusive of Value Added Tax which where applicable will be paid by the Licensee to UCLB in addition;
- 5.12.2 shall be paid in pounds sterling in cash by transferring an amount in aggregate to the following Account name: UCL Business Plc, Sort Code: 20 10 53, Account number: 30782270, Address: Barclays Bank Plc, PO Box 11345, London, W12 8GG, and in the case of income or amounts received by the Licensee or its Affiliates in a currency other than pounds sterling, the royalty shall be calculated in the other currency and then converted into equivalent pounds sterling at the relevant daily spot rate for that currency as quoted in the Financial Times newspaper on the last business day of the quarter in relation to which the royalties are payable;
- 5.12.3 will be made without any set-off, deduction or withholding except as may be required by law. If the Licensee is required by law to make any deduction or to withhold any part of any amount due to UCLB under this Agreement, the Licensee will give to UCLB proper evidence of the amount deducted or withheld and payment of that amount to the relevant taxation authority, and will do all things in its power to enable or assist UCLB to claim exemption from or, if that is not possible, to obtain a credit for the amount deducted or withheld under any applicable double taxation or similar agreement from time to time in force; and
- 5.12.4 shall be made by the due date, failing which UCLB may charge interest on any outstanding amount on a daily basis at a rate equivalent to [\*\*\*]% above the Bank of England pound sterling base rate then in force in London.

## 5.13 Royalty Statements

The Licensee shall, in respect of each Licensed Technology, send to UCLB at the same time as each royalty payment is made in accordance with Clauses 5.6 and 5.7 a statement setting out for the relevant calendar quarter:

- 5.13.1 in respect of each territory or region in which Licensed Products are sold:
  - (a) the types of Licensed Product sold;
  - (b) the quantity of each type sold;
  - (c) the total invoiced price for each type of Licensed Product sold;
  - (d) where relevant, details of any Licensed Products that have been sold other than on arm's length terms for a cash consideration, including the relevant open market price or (if not available) the reasonable price attributed thereto;
  - (e) the amounts deducted from the Net Sales Value as referred to in paragraph (i) to (iv) of that definition (broken down on a product by product and category by category basis); and
  - (f) the aggregate royalties on Net Sales Value due to UCLB.;
- 5.13.2 a breakdown of all Net Receipts,

in each case expressed both in local currency and pounds sterling and showing the conversion rates used, during the period to which the royalty payment relates.

# 5.14 Records

In respect of each Licensed Technology:

- 5.14.1 The Licensee shall keep at its normal place of business detailed and up to date records and accounts showing the quantity, description and invoiced price or non-cash consideration for all Licensed Products sold by it or its Affiliates or on its or its Affiliates' behalf, and the amount of Net Receipts, broken down in each case on a country by country basis, and being sufficient to ascertain the payments due to UCLB under this Agreement.
- The Licensee shall make such records and accounts available, on reasonable notice, for inspection during business hours by an independent chartered accountant nominated by UCLB for the purpose of verifying the accuracy of any statement or report given by the Licensee to UCLB under Clause 5.14.1. The Licensee shall co-operate reasonably with any such accountant, and shall promptly provide all information and assistance reasonably requested by such accountant. The accountant shall be required to keep confidential all information learnt during any such inspection, and to disclose to UCLB only such details as may be necessary to report on the accuracy of the Licensee's statement or report. UCLB shall be responsible for the accountant's charges unless the accountant certifies that there is an inaccuracy of more than [\*\*\*]% ([\*\*\*] percent) in any royalty statement, in which case the Licensee shall pay his charges in respect of that inspection.

5.14.3 The Licensee shall ensure that UCLB has the same rights as those set out in this Clause 5.14 in respect of the Licensee's Affiliates and Sub-licensees.

The Licensee shall co-operate with UCLB in good faith to resolve any discrepancies identified during any such inspection and [\*\*\*], together with interest on late payment as specified in Clause 5.12.4, within [\*\*\*] following receipt of a copy of the independent chartered accountant's report.

## 5.15 Accounting Standards

Where this Agreement requires a financial calculation to be made or an action to be taken, such calculation or action will be made or taken in accordance with the generally accepted accounting principles from time to time approved by the United Kingdom's Accounting Standards Board, or any successor body, applicable as at the date on which such calculation or action is made or taken.

# 6. **COMMERCIALISATION**

## 6.1 **General Diligence**

The Licensee shall in respect of each Licensed Technology, use Diligent Efforts to develop and commercially exploit Licensed Products throughout the Territory (including obtaining all and any regulatory approvals which may be required to market and sell the Licensed Products) and to maximise sales for the benefit of both Parties.

### 6.2 **Competing Activities**

The Licensee shall notify UCLB in confidence if it or any of its Affiliates or its Sub-licensees commences any marketing, sale or commercialisation of any Competing Product or enters into an agreement with any other person with respect to any such activities.

### 6.3 **Development Plan**

The current Development Plan for the Licensed Technology is shown in each Licensee Addendum (the "Current Development Plan"). Within six (6) months of the Effective Date of the relevant Licence Addendum, the Licensee will provide for each Licensed Technology, an updated plan for developing and commercialising Licensed Products (the "Updated Development Plan"). The Updated Development Plan shall include development milestones events mutually agreed by the Parties and shall form part of the relevant Licence Addendum and this Agreement. The Parties shall negotiate in good faith to reach agreement on such development milestones. In the event that the Licensee fails to provide the Updated Development Plan or the Parties fail to agree development milestones, despite negotiating in good faith, within such six month period, UCLB may in its sole and absolute discretion terminate the relevant Licence Addendum in accordance with Clause 11.5.1. The Licensee shall provide to UCLB on each anniversary of the Effective Date of the relevant Licence Addendum a written update to the Updated Development Plan that shall:

- 6.3.1 report on all activities conducted under this Agreement by the Licensee and its Affiliates and Sub-licensees since the Effective Date of the relevant Licence Addendum or the date of the previous update (as appropriate);
- 6.3.2 (where applicable) set out the milestone events achieved since the Effective Date of the relevant Licence Addendum or the date of the previous update (as appropriate) and the Licensee's reasonable estimate of the dates for achieving any future milestone events;
- 6.3.3 set out the current and projected activities being taken or planned to be taken by the Licensee and its Affiliates and Sub-licensees to bring Licensed Products to market, and to maximise the sale of Licensed Products in the Territory; and
- 6.3.4 set out the Licensee's projected sales of Licensed Products (based on the Licensee's current forecasts) for each of the next [\*\*\*] ([\*\*\*]) years following the date of the report.

UCLB's receipt or approval of any update to the Updated Development Plan shall not be taken to waive or qualify the Licensee's obligations under Clause 6.1.

### 6.4 **Annual Meeting**

In respect of the Licensed Technology, the Licensee will on UCLB's request meet with UCLB at least once per calendar year, following the submission of the update to the relevant Development Plan pursuant to Clause 6.3, to discuss progress with development and commercialisation of the Licensed Technology and where relevant the Licensee's efforts to maximise sales of Licensed Products.

### 6.5 **Development Milestones**

In addition to the Licensee's obligations under Clause 6.1, the Licensee shall for each Licensed Technology use Diligent Efforts to achieve the development milestone events specified in the relevant Licence Addendum by the dates set out therein or as later agreed between the Parties in accordance with Clause 6.3, where applicable.

### 6.6 Reporting of First Commercial Sale

The Licensee will, for each Licensed Technology, promptly notify UCLB in writing of the first commercial sale of each Licensed Product in each country within the Territory.

### 6.7 **Reporting for Impact Purposes**

6.7.1 The Licensee acknowledges that part of UCLB's purpose in licensing the Licensed Technologies to the Licensee pursuant this Agreement is to ensure that the Licensed Technologies are made available for use and commercial exploitation with the intention of benefitting society and the economy. In order to enable UCL and UCL to monitor the benefit that they are providing, and to enable UCL to demonstrate the impact of its research activities, to society and the economy, the Licensee will upon request provide to UCLB [\*\*\*], a written report describing in reasonable detail how it has used each Licensed Technology, and the societal and economic benefits generated therefrom.

6.7.2 UCLB shall notify and seek permission from the Licensee in advance, in writing if it wishes to use any written reports received from the Licensee (and the information contained therein) pursuant to Clause 6.7.1 in applications for research or other grant related funding and in submissions to Higher Education funding bodies such as HEFCE and/ or HEIF (or any replacements for either of those entities) and like entities, supplying a written copy of the application for research or other grant related funding or submission (or the relevant sections thereof). The Licensee will respond to UCLB in writing within [\*\*\*] ([\*\*\*]) days of receipt of such written information and subject to the removal of any confidential information as notified in such written request by the Licensee, UCLB and UCL shall be entitled to submit the approved applications for research or other grant related funding and in submissions to Higher Education funding bodies such as HEFCE and/or HEIF (or any replacements for either of those entities) and like entities.

### 6.8 Quality

The Licensee shall ensure that all of the Licensed Products marketed by it and its Affiliates and Sub-licensees are of satisfactory quality and comply with all applicable laws and regulations in each part of the Territory.

## 6.9 Marking of Licensed Products

To the extent permitted under the laws of any country, the Licensee shall mark and cause its Affiliates and Sub-Licensees to mark each Licensed Product with the number of each issued Patent which applies to the Licensed Product and a statement that such Licensed Products are sold under licence from UCL Business plc.

### 6.10 Disposals of Licensed Products for Free

Notwithstanding the terms of Clause 6.1, the Licensee shall be entitled to supply a reasonable number of Licensed Products to third parties free of charge as promotional items for the purpose of establishing a market for the Licensed Products in the relevant country or territory or for evaluation and testing purposes, provided that the quantity of Licensed Products supplied for free in each country or territory is not excessive and is in line with normal industry practice in such country or territory. Any Licensed Products disposed of to third parties free of charge in accordance with this Clause 6.10 shall not be taken into account for the purposes of calculating Net Sales Value.

## 6.11 Referral to Expert

If UCLB considers at any time during the period of this Agreement that the Licensee has failed to comply with its obligations under Clause 6.1, 6.3 or 6.5 in relation to any Licensed Technology, then the matter shall be referred to an independent expert to answer the following questions:

- 6.11.1 whether the Licensee has complied with its obligations under Clause 6.1, 6.3 or 6.5 in relation to the relevant Licensed Technology; and if not
- 6.11.2 what specific action the Licensee should have taken and/or now needs to take ("Specific Action") in order to fulfil such obligations and within what period the Specific Action should be taken ("Action Period").

The independent expert shall be appointed in accordance with the provisions of Schedule 2 and his decision shall be final and binding on the Parties.

### 6.12 Consequences of Expert's Decision

If the expert determines that the Licensee has failed to comply with its obligations under Clause 6.1, 6.3 or 6.5 in relation to the relevant Licensed Technology, and if the Licensee fails to take the Specific Action within the Action Period, UCLB shall be entitled, by giving, at any time within [\*\*\*] ([\*\*\*]) months after the end of that Action Period, not less than [\*\*\*] ([\*\*\*]) months' notice, to (a) convert the licence granted under the relevant Licence Addendum into a non-exclusive licence or (b) terminate the relevant Licence Addendum in accordance with Clause 11.5.2.

### 7. ACCESS TO MEDICINES AND ETHICAL LICENSING

# 7.1 **General Diligence**

The Licensee agrees to use Diligent Efforts to develop and commercially exploit Licensed Products in a manner consistent with ethical and socially responsible licensing principles, including requiring all Sub-licensees and other parties involved in the development and commercial exploitation of Licensed Products to agree in writing to comply with ethical and socially responsible licensing principles.

## 7.2 Supply to Developing Countries

## 7.2.1 Supply by the Licensee

The Licensee shall use Diligent Efforts to supply the Licensed Products to customers in At-Cost Markets at a Cost-Based Price and to meet market demand for the Licensed Products in those markets.

### 7.2.2 Sub-Licensing in Developing Country markets

If the Licensee is unable to supply the Licensed Product at a Cost-Based Price in any At-Cost market and to meet market demand for the Licensed Products in those market, it shall use Diligent Efforts to license one or more Developing Country Manufacturers on Reasonable Developing Country License Terms to manufacture, distribute and sell the Licensed Product at a Cost-Based Price in that At-Cost Market.

## 7.3 **Reporting**

The Licensee shall keep UCLB regularly updated regarding the Licensee's efforts to supply the Licensed Products in accordance with the requirements outlined in Clauses 7.1 and 7.2.

## 7.4 Step In Rights

- 7.4.1 If at any time UCLB acting reasonably considers that the Licensee is not meeting its obligations under Clauses 7.1 and 7.2 in relation to the supply of the Licensed Products to customers in At-Cost Markets, UCBL may be written notice require the Licensee to seek one or more third parties to develop, commercialise and supply the Licensed Products to customers in At-Cost Markets.
- 7.4.2 If the Licensee following a written requirement from UCLB refuses to grant a sublicense to or is unable to identify a third party to develop, commercialise and supply the Licensed Products to customers in At-Cost Markets, then UCLB notwithstanding the rights granted to the Licensee under this Agreement shall have the right to seek a third party and/ or to grant to a third party a license to manufacture, have manufactured, use, sell, offer for sale and import the Licensed Products for supply in the At-Cost market on Reasonable Developing Country License Terms.

### 8. COMPLIANCE WITH LAWS

## 8.1 General Compliance with Laws

The Licensee will at all times (and will ensure its Affiliates and Sub-licensees) comply with all legislation, rules, regulations and statutory requirements applying to and obtain any consents necessary for its use of each Licensed Technology, the development, manufacture, and sale of Licensed Products and the provision of Licensed Services in any country or territory.

## 8.2 Bribery Act

The Licensee shall (and shall procure that any persons associated with it engaged in the performance of this Agreement including its Affiliates and Sub-licensees shall):

8.2.1 comply with all applicable laws and codes of practice relating to anti-bribery and anti-corruption including the Bribery Act 2010 and without prejudice to the foregoing generality, shall not engage in any activity, practice or conduct which would constitute an offence under sections 1, 2 or 6 of the Bribery Act 2010 or do or omit to do any act that will cause or lead UCLB to be in breach of the Bribery Act 2010;

- 8.2.2 comply with UCLB's ethics, anti-bribery and anti-corruption policies as notified to the Licensee from time to time and have, maintain in place and enforce throughout the term of this Agreement adequate procedures to ensure compliance with Clause 8.2.1; and
- 8.2.3 promptly report to UCLB any request or demand for any undue financial or other advantage of any kind received in connection with the performance of this Agreement.

For the purpose of this Clause 8.2, the meaning of adequate procedures and whether a person is associated with another person shall be determined in accordance with the Bribery Act 2010 (and any guidance issued under section 9 of that Act). Breach of this Clause 8.2 shall be deemed a material breach of this Agreement entitling UCLB to terminate under Clause 11.3.1.

### 8.3 **Export Control Regulations**

The Licensee shall ensure that, in using the Licensed Technologies and in selling Licensed Products, it and its Affiliates, employees, sub-contractors and Sub-licensees comply fully with any United Nations trade sanctions or EU or UK legislation or regulation, from time to time in force, which impose arms embargoes or control the export of goods, technology or software, including weapons of mass destruction and arms, military, paramilitary and security equipment and dual-use items (items designed for civil use but which can be used for military purposes) and certain drugs and chemicals.

### 9. INTELLECTUAL PROPERTY

### 9.1 **Obtain and Maintain the Patents**

- 9.1.1 The Licensee shall be responsible for the drafting, filing, prosecution and maintenance of all of the Patents for each Licenced Technology exclusively licensed to the Licensee subject to Clause 2.4, at the Licensee's cost and expense. Subject to resource availability, UCLB shall use commercially reasonable efforts to provide such assistance as the Licensee may request to prosecute and maintain the Patents[\*\*\*] that may be incurred in providing such assistance. For the avoidance of doubt, the provisions of this Clause 9 shall also extend to any patents filed in respect of the Specified Technology pursuant to Clause 2.6 after the Commencement Date.
- 9.1.2 The Patents for each Licensed Technology will be filed, prosecuted and maintained in the countries and territories set out in Appendix 2 to the relevant Licence Addendum. The Licensee shall notify UCLB of any decisions as to which (if any) additional countries to file and maintain Patents in.

- 9.1.3 The Licensee shall consult with UCLB in relation to all material changes to the patent claims or specifications that would have the effect of reducing or limiting the scope of the Patents, and not make any such changes without the prior written consent of UCLB. Such consent shall not be unreasonably withheld or delayed provided that UCLB has been given as much notice as is practicable, and in any event no less than [\*\*\*] days' notice (or such shorter period for response dictated by the relevant patent office) of such proposed changes, and has been given an opportunity to file divisionals, continuations and/or such other types of protection to cover any claims or subject matter that the Licensee intends to remove from the scope of the Patents. If UCLB fails to respond before the end of the [\*\*\*] day period (or such shorter period for response dictated by the relevant patent office), the Licensee may proceed with the proposed changes to the patent claims or specifications. The Licensee will ensure that UCLB receives copies of all correspondence to and from Patent Offices in respect of the Patents for each Licensed Technology, including copies of all documents generated in or with such correspondence, and shall be given reasonable notice (or such shorter period for response dictated by the relevant patent office) of and the opportunity to participate in any conference calls or meetings with the Licensee's patent attorneys in relation to the drafting, filing, prosecution and maintenance of the Patents, so that UCLB may be continuously informed of progress with the drafting, filing, prosecution and maintenance of the Patents. Such involvement of UCLB under this Clause 9.1.3 shall be at UCLB's cost and expense.
- 9.1.4 If the Licensee wishes to abandon any application contained with the Patents for any Licensed Technology or not to maintain any such Patent, it shall give [\*\*\*] ([\*\*\*]) months' prior written notice to UCLB and on the expiry of such notice period the relevant Licence Addendum shall terminate and the licences of the relevant Patents granted to the Licensee under this Agreement shall cease.
- 9.1.5 In the event that any of rights to the Licenced Technology granted hereunder become non-exclusive, responsibility for the drafting, filing, prosecution and maintenance of all of the Patents for such Licenced Technology shall revert to UCLB.

#### 9.2 **Infringement of the Patents**

- 9.2.1 Each Party shall inform the other Party promptly if it becomes aware of any infringement or potential infringement of any of the Patents for each Licensed Technology in the relevant Field or any unauthorised use of the Know-how or any challenge to the validity or ownership of the Patents, and the Parties shall consult with each other to decide the best way to respond to such infringement, unauthorised use or challenge.
- 9.2.2 In relation to each Patent exclusively licensed to the Licensee subject to Clause 2.4, the Licensee shall have the primary obligation and right to take action against any third party alleged to be infringing the Patents for each Licensed Technology or making unauthorised use of the Know-how to defend the Patents against challenges to validity or ownership at its sole expense, provided that:

- (a) UCLB shall on the Licensee's request cooperate with the Licensee in such action [\*\*\*]; and
- (b) subject to Clauses 9.2.3 and 9.2.5, the Licensee shall be solely responsible for the conduct of the action or for settlement thereof and shall be entitled to all damages received from such action, subject to Clause 9.2.4.
- 9.2.3 Before starting or defending or settling any legal action under Clause 9.2.2, the Licensee shall consult with UCLB as to the advisability of the action or defence or settlement, its effect on the good name of UCLB, the public interest, and how the action or defence should be conducted.
- 9.2.4 The Licensee shall [\*\*\*] in such action or defence.
- 9.2.5 UCLB shall if reasonably requested by the Licensee agree to be joined in any suit to enforce such rights or will take such action in its own name [\*\*\*] and shall have the right to be separately represented by its own counsel [\*\*\*]. Notwithstanding the foregoing, [\*\*\*].
- 9.2.6 If the Licensee is unsuccessful in persuading the alleged infringer to desist within [\*\*\*] ([\*\*\*]) months of the Licensee first becoming aware of any potential infringement of the Patents for any Licensed Technology or fails to initiate an infringement action within [\*\*\*] ([\*\*\*]) months of becoming aware of such infringement, UCLB shall have the right, at its sole discretion, to prosecute such infringement under its sole control [\*\*\*].

## 9.3 Infringement of Third Party Rights

- 9.3.1 If any warning letter or other notice of infringement is received by a Party, or legal suit or other action is brought against a Party, alleging infringement of third party rights in the manufacture, use or sale of any Licensed Product or use of any Patents or any Licensed Technology, that Party shall promptly provide full details to the other Party, and the Parties shall discuss the best way to respond.
- 9.3.2 In relation to each Patent exclusively licensed to the Licensee, the Licensee shall have the right but not the obligation to defend such suit to the extent it relates to the Licensee's or its Affiliates or Sub-licensee's activities in the relevant Field and shall have the right to settle with such third party, provided that [\*\*\*].

### 10. WARRANTIES AND LIABILITY

### 10.1 Warranties by UCLB

UCLB warrants and undertakes as follows in respect of each Licensed Technology and subject to any disclosures and exceptions set out in the relevant Licence Addendums, to its reasonable knowledge and without having undertaken any due and careful enquires whether specific or general in nature:

- 10.1.1 it is the registered proprietor of, or applicant for, the relevant Patents; and
- 10.1.2 it has the authority to grant the licences under this Agreement and the relevant Licence Addendum.
- 10.1.3 so far as it is aware (having made no enquiry of any third parties or conducted any freedom to operate searches), use and exploitation of the Patents will not infringe the intellectual property rights of any third party.

### 10.2 Warranties by the Licensee

The Licensee warrants and undertakes that in respect of the Licensed Technology:

- 10.2.1 it has the right and authority to enter into this Agreement and the relevant Licence Addendum;
- 10.2.2 so far as it is aware (having made no enquiry of any third parties), use and exploitation of the Patents will not infringe the intellectual property rights of any third party;
- 10.2.3 neither it nor any of its Affiliates is currently researching, developing, marketing, selling or otherwise commercialising any Competing Product ("Competing Activities"), nor has any of them entered into an agreement with any other person with respect to any Competing Activities; and
- 10.2.4 it shall notify UCLB if it or any of its Affiliates or its Sub-licensees commences any Competing Activities or enters into an agreement with any other person with respect to any Competing Activities.

### 10.3 Acknowledgements

The Licensee acknowledges that in respect of each Licensed Technology:

- the Licensed Technology, including inventions claimed in the Patents, and the Know-how, are at an early stage of development.

  Accordingly, specific results cannot be guaranteed and any results, materials, information or other items (together "Delivered Items") provided under this Agreement are provided "as is" and without any express or implied warranties, representations or undertakings. As examples, but without limiting the foregoing, UCLB does not give any warranty that Delivered Items are of merchantable or satisfactory quality, are fit for any particular purpose, comply with any sample or description, or are viable, uncontaminated, safe or non-toxic.
- 10.3.2 UCLB has not performed any searches or investigations into the existence of any third party rights that may affect the relevant Licensed Technology.

## 10.4 No Other Warranties

- 10.4.1 Each of the Parties acknowledges that, in entering into this Agreement, it does not do so in reliance on any representation, warranty or other provision except as expressly provided in this Agreement, and any conditions, warranties or other terms implied by statute or common law are excluded from this Agreement to the fullest extent permitted by law.
- 10.4.2 Without limiting the scope of Clause 10.4.1, UCLB does not make any representation nor give any warranty or undertaking:
  - (a) as to the efficacy or usefulness of the Licensed Technologies; or
  - (b) as to the scope of any of the Patents or that any of the Patents is or will be valid or (in the case of an application) will proceed to grant; or
  - (c) that the use of any of the Licensed Technologies, the manufacture, sale or use of the Licensed Products, or the exercise of any of the rights granted under this Agreement will not infringe any intellectual property or other rights of any other person; or
  - (d) that the Know-how or any other information communicated by UCLB to the Licensee under or in connection with this Agreement will produce Licensed Products of satisfactory quality or fit for the purpose for which the Licensee intended or that any product will not have any defect, latent or otherwise, and whether or not discoverable by inspection; or
  - (e) as imposing any obligation on UCLB to bring or prosecute actions or proceedings against third parties for infringement or to defend any action or proceedings for revocation of any of the Patents; or
  - (f) as imposing any liability on UCLB in the event that any third party supplies Licensed Products to customers located in the Territory; or
  - (g) that there will be no similar or competitive products manufactured, used, sold or supplied by any third party in the Territory.

# 10.5 Responsibility for Development of Licensed Products and Licensed Services

The Licensee shall be exclusively responsible for its and its Affiliates' and Sub-licensees' use of the Licensed Technology, the technical and commercial development and manufacture of Licensed Products and for incorporating any modifications or developments thereto that may be necessary or desirable, for all Licensed Products sold or supplied, notwithstanding any consultancy services or other contributions that UCLB and/or UCL may provide in connection with such activities.

## 10.6 **Indemnity**

The Licensee shall indemnify each of UCLB and UCL, and each of their respective officers, directors, Council members, employees and representatives (together, the "Indemnitees") against all Claims that may be asserted against or suffered by any of the Indemnitees and which relate to:

- 10.6.1 the use by the Licensee or any of its Affiliates or Sub-licensees of any of the Licensed Technology; or
- 10.6.2 use of the Licensed Technology by or on behalf of the Licensee or any of its Affiliates or Sub-licensees; or
- 10.6.3 the development, manufacture, use, marketing or sale of, or any other dealing in, any of the Licensed Products, by or on behalf of the Licensee or any of its Affiliates or Sub-licensees, or subsequently by any customer or any other person, including claims based on product liability laws.

The indemnity given by the Licensee to each Indemnitee under this Clause will not apply to any Claim to the extent that it is attributable to the gross negligence, reckless misconduct or intentional misconduct of that Indemnitee.

## 10.7 Limitations of Liability

- 10.7.1 To the extent that UCLB or any of its Affiliates has any liability in contract, tort, or otherwise under or in connection with this Agreement, including any liability for breach of warranty, their liability shall be limited in accordance with the following provisions of this Clause 10.7.
- 10.7.2 The aggregate liability of UCLB and any of its Affiliates shall be limited to the total income that UCLB has received from the Licensee pursuant to this Agreement (but excluding any other costs or expenses associated with drafting, filing, prosecuting, maintaining or defending any Patents or providing any assistance to the Licensee) during the period of [\*\*\*] ([\*\*\*]) years preceding the date on which the liability arises, or fifty thousand pounds (£50,000) sterling, whichever is the higher.
- 10.7.3 The liability of the Licensee shall be limited to the limit of its insurance as set out in Clause 10.8.1, except that in the case of product liability, the liability of the Licensee under this Agreement shall be unlimited.
- 10.7.4 In no circumstances shall either Party or any Indemnitee be liable for any loss, damage, costs or expenses of any nature that is (a) of an indirect, special or consequential nature or (b) any loss of profits (whether direct or indirect), revenue, business opportunity or goodwill, which arises directly or indirectly from that Party's breach or non performance of this Agreement, or negligence in the performance of this Agreement or from any liability arising in any other way out of the subject matter of this Agreement even if the Party bringing the claim has advised the other Party or the relevant Indemnitee of the possibility of those losses arising, or if such losses were within the contemplation of the Parties or the Indemnitee.

Nothing in this Agreement excludes either Party's liability to the extent that it may not be so excluded under applicable law, including any such liability for death or personal injury caused by that Party's negligence, or liability for fraud or fraudulent misrepresentation.

### 10.8 Insurance

- 10.8.1 The Licensee shall take out with a reputable insurance company and maintain at all times during the term of this Agreement public and product liability and professional indemnity insurance including against all loss of and damage to property (whether real, personal or intellectual) and injury to persons including death arising out of or in connection with this Agreement and the Licensee's and its Affiliates' and Sub-licensees' use of the Licensed Technology and as and when relevant use, sale of or any other dealing in any of the Licensed Products. Such insurances may be limited in respect of one claim provided that such limit must be at least [\*\*\*] pounds (£[\*\*\*]) sterling, unless the Licensee commences any business in manufacturing, distribution, supply or otherwise make available to the public any products, in which case such limit must be at least [\*\*\*] pounds (£[\*\*\*]) sterling. Such insurance shall continue to be maintained for a further [\*\*\*] years from the end of the last Licence Addendum hereunder to terminate.
- 10.8.2 The Licensee will produce to UCLB at all times upon demand proof that the insurance cover required pursuant to Clause 10.8.2 is in force and evidence that all premiums have been paid up to date. If UCLB becomes aware that the Licensee has failed to maintain the insurance required pursuant to Clause 10.8.2 UCLB may effect such insurance and the Licensee will reimburse UCLB for the reasonable cost of effecting and maintaining such insurance on demand.

## 11. DURATION AND TERMINATION

## 11.1 Commencement and Termination by Expiry (General)

This Agreement (excluding the Licence Addendums) shall come into effect on the Commencement Date and, unless terminated earlier in accordance with this Clause 11 or Clause 12.1.2, shall continue in force until the date on which the last Licence Addendum entered into hereunder has expired or terminated.

# 11.2 Commencement and Termination by Expiry (Licence Addendums)

[\*\*\*]

## 11.3 Early Termination (General)

Each Party (the "Terminating Party") may terminate this Agreement at any time by notice in writing to the other Party ("Other Party"), such notice to take effect as specified in the notice:

- if the Other Party is in material breach of this Agreement and, in the case of a breach capable of remedy within thirty (30) days, the breach is not remedied within thirty (30) days of the Other Party receiving notice specifying the breach and requiring its remedy or where the breach relates to non-payment of a sum due under this Agreement, the sum is not paid in full within fourteen (14) days following the Other Party receiving notice specifying the non payment and requiring payment in full; or
- 11.3.2 if:
  - (a) the Other Party becomes insolvent or unable to pay its debts as and when they become due;
  - (b) an order is made or a resolution is passed for the winding up of the Other Party (other than voluntarily for the purpose of solvent amalgamation or reconstruction);
  - (c) a liquidator, administrator, administrative receiver, receiver or trustee is appointed in respect of the whole or any part of the Other Party's assets or business;
  - (d) the Other Party makes any composition with its creditors;
  - (e) the Other Party ceases to continue its business; or
  - (f) any event analogous to the events referred to in paragraphs (a) to (e) above occurs in any other jurisdiction.

The Terminating Party may, at its discretion, choose not to terminate any or all of the Licence Addendums notwithstanding termination of this Agreement, by specifying such in its notice to the Other Party when terminating this Agreement. The relevant terms of this Agreement shall continue in force thereafter to the extent necessary to give effect to the terms of any Licence Addendum(s) which are not terminating until the last such Licence Addendum either expires or is terminated.

- 11.4 UCLB may terminate this Agreement by giving written notice to the Licensee, such termination to take effect forthwith or as otherwise stated in the notice:
  - 11.4.1 if there is any change of Control of the Licensee involving the categories of persons or Affiliates of persons prohibited by Clause 2.3; or

- the Licensee is in persistent breach of the Agreement and where the Parties have failed to agree a mechanism to remedy the persistent nature of such breaches within a reasonable period following UCLB notifying the Licensee of the persistent breach and requesting that the Licensee enters into discussions with UCLB as to mechanisms for remedying the persistent breaches or if the Parties have agreed a mechanism to remedy the persistent breach but that mechanism if not fully complied with by the Licensee; or
- 11.4.3 the Licensee is in material breach of the Agreement more than twice in any 24 month period, even if said breaches have been remedied; or
- 11.4.4 if the Licensee or its Affiliate commences legal proceedings, or assists any third party to commence legal proceedings, to challenge the validity or ownership of any of the Patents; or
- 11.4.5 if the Licensee shall enter into any sub-licence with any of the categories of persons or Affiliates of persons prohibited by Clause 2.3 which may, adversely affect UCL's and/or UCLB's reputation; or
- 11.4.6 if the Licensee is in material breach of the Shareholders' Agreement, and said breach is not remedied within 30 days of UCLB notifying the Licensee of said breach and the remedial actions required (acting reasonably) as the case may be.

UCLB may, at its discretion, choose not to terminate any or all of the Licence Addendums notwithstanding termination of this Agreement, by specifying such in its notice to the Licensee when terminating this Agreement. The relevant terms of this Agreement shall continue in force thereafter to the extent necessary to give effect to the terms of any Licence Addendum(s) which are not terminating until the last such Licence Addendum either expires or is terminated.

## 11.5 Early Termination (Licence Addendums)

- 11.5.1 Each Party may terminate each Licence Addendum (separately from this Agreement or any other Licence Addendum) at any time by notice in writing to the Other Party, such notice to take effect as specified in the notice, if the Other Party is in material breach of the relevant Licence Addendum and, in the case of a breach capable of remedy within thirty (30) days, the breach is not remedied within thirty (30) days of the Other Party receiving notice specifying the breach and requiring its remedy, or where the breach relates to non-payment of a sum due under the relevant Licence Addendum, the sum is not paid in full within fourteen (14) days following the Other Party receiving notice specifying the non-payment and requiring payment in full.
- 11.5.2 UCLB may terminate each Licence Addendum (separately from this Agreement or any other Licence Addendum) by giving written notice to the Licensee, such termination to take effect forthwith or as otherwise stated in the notice:

- (a) if the Licensee fails to achieve any of the milestone events described in the Licensed Addendums provided that if achievement of any of the milestone events should be compromised due to technical, legal or regulatory issues, the Parties shall first meet and UCLB will work with the Licensee to manage the delivery schedule and provided that the Licensee is using Diligent Efforts to correct the issues, the applicable deadline in the relevant Licence Addendum shall be extended by six (6) months or such other time period as shall be agreed between the Parties in writing after which if the Licensee has not achieved the milestone UCLB shall be entitled, subject to Clauses 6.11 and 6.12, to terminate the Licence Addendum by giving written notice to the Licensee; or;
- (b) if the Licensee is in persistent breach of the relevant Licence Addendum and where the Parties have failed to agree a mechanism to remedy the persistent nature of such breaches within a reasonable period following UCLB notifying the Licensee of the persistent breach and requesting that the Licensee enters into discussions with UCLB as to mechanisms for remedying the persistent breaches or if the Parties have agreed a mechanism to remedy the persistent breach but that mechanism if not fully complied with by the Licensee;
- (c) if the Licensee is in material breach of the relevant Licence Addendum more than twice in any 24 month period, even if said breaches have been remedied;
- (d) in accordance with the provisions of Clauses 6.12 or 9.1;
- (e) if the Licensee or its Affiliate or its Sub-licensee commences legal proceedings, or assists any third party to commence legal proceedings, to challenge the validity or ownership of any of the Patents; or
- (f) in accordance with any other provision as may be specified in the relevant Licence Addendum.
- 11.6 A Party's right of termination under this Agreement, and the exercise of any such right, shall be without prejudice to any other right or remedy (including any right to claim damages) that such Party may have in the event of a breach of contract or other default by the other Party.

## 11.7 Consequences of Termination (General)

- 11.7.1 Upon termination or expiry of this Agreement howsoever arising:
  - (a) all Licence Addendums shall terminate forthwith; and

- (b) each Party shall upon the written request of the other Party, return or destroy any documents or other materials that are in its or its Affiliates possession or under its or their control and that contain the other Party's Confidential Information provided always that each Party and its Affiliates shall be entitled to retain such Confidential Information of the other Party that relates to any Licence Addendum that is not terminating at the same time as the rest of this Agreement until termination or expiry of the relevant Licence Addendum.
- 11.7.2 Upon termination of this Agreement for any reason the provisions of Clauses 1, 2.3, 2.5, 3.2 to 3.5, 4, 5 (in respect of amounts paid and payable to UCLB in respect of the period up to an including the date of termination), 6.7, 8, 10, 11.6, 11.7, 11.8 and 12 of this Agreement shall remain in force.

## 11.8 Consequences of Termination (Licence Addendums).

- 11.8.1 Upon expiry of each Licence Addendum, and subject to all royalties and any other sums due to UCLB in respect of the Licensed Technology having been duly paid, the Licensee shall have a fully paid up licence to the Licensed Technology of the same scope as set forth in Clause 2.1 without any further obligation to pay any further sums to UCLB under Clause 5. Notwithstanding the foregoing the Licensee acknowledges that once each Patent expires or is abandoned or withdrawn or allowed to lapse in any country or territory, third parties in that country or territory will be entitled to use the inventions claimed in the relevant Patent and that accordingly the relevant licence granted to the Licensee will no longer be exclusive in that country or territory.
- 11.8.2 Upon termination of each Licence Addendum for any reason other than as set forth in Clause 11.2:
  - (a) the Licensee and its Affiliates and Sub-licensees shall be entitled to sell, use or otherwise dispose of (subject to payment of royalties under Clause 5) any unsold or unused stocks of the relevant Licensed Products for a period of [\*\*\*] ([\*\*\*]) months following the date of termination;
  - (b) subject to paragraph (a) above, any license that has not become fully paid-up in accordance with Clause 11.8.1 shall terminate and the Licensee and its Affiliates (and subject to Clause 2.3, its Sub-licensees) shall no longer be licensed to use or otherwise exploit the relevant Licensed Technology, in so far and for as long as any of the relevant Patents remains in force and the relevant Know-how remains confidential;
  - (c) the Licensee shall consent to the cancellation of any formal licence granted to it, or of any registration of it in any register, in relation to any of the relevant Patents;
  - (d) the Licensee will, promptly on UCLB's request, provide (and will ensure that its patent agents provide) to UCLB all information, documentation and assistance (including executing documents) which UCLB may reasonably require to enable it to continue with the drafting, filing, prosecution and maintenance of the relevant Patents;

- (e) except as set out in Clause 2.3, all sub-licences of the relevant Licensed Technology granted by the Licensee will automatically terminate;
- (f) each Party shall upon the written request of the other Party, return or destroy any documents or other materials that are in its or its Affiliates possession or under its or their control and that contain the other Party's Confidential Information which relates to the relevant Licensed Technology;
- 11.8.3 Upon termination by expiry of each Licence Addendum under Clause 11.2, UCLB and its Affiliates shall be free to disclose the Know-how licensed under such Licence Addendum to third parties.
- 11.8.4 Upon termination of each Licence Addendum under Clause 11.5 by UCLB or as a result of termination of this Agreement under Clause 11.3 by UCLB, in the event that UCLB would be unable, absent a licence from the Licensee, to use or permit others to use or to exploit or permit others to exploit the relevant Licensed Technology without infringing intellectual property rights in any invention developed by the Licensee, whether solely or jointly with others ("Blocking Invention"), the Licensee shall be deemed to have granted UCLB the irrevocable non-exclusive right to use, exploit and permit others to use and exploit the Blocking Invention only in conjunction with the relevant Licensed Technology. The Licensee shall at the request of UCLB provide (and will ensure that its patent agents provide) to UCLB all information, documentation and assistance (including executing documents) which UCLB may reasonably require to enable it to continue with the drafting, filing, prosecution and maintenance of the Patents licensed under such Licence Addendum;
- 11.8.5 Upon termination of each Licence Addendum under Clause 11.5 by UCLB or as a result of termination of this Agreement under 11.3 by UCLB, the Licensee shall, to the extent it is able to do so without being in breach of any obligation owed to a third party, disclose to UCLB full details of any and all Intellectual Property generated at any time by or on behalf of the Licensee as a result of the exercise of the Licensee's rights under this Licence Addendum ("Licensee IP") and, upon UCLB's written request within [\*\*\*] ([\*\*\*]) days following such disclosure, negotiate in good faith to agree the terms of an exclusive or non-exclusive licence to UCLB (as UCLB may request) under the Licensee IP. If the Parties fail to agree the terms of such a licence within [\*\*\*] days following commencement of such negotiation, despite negotiating in good faith, UCLB's rights under this Clause 11.8.5 shall lapse.
- 11.8.6 Upon termination of each Licence Addendum for any reason the provisions of Clauses 1, 3 (in respect of amounts paid and payable to UCLB in respect of the period up to an including the date of termination) and 5 of the Licence Addendum shall remain in force.

## 12. **GENERAL**

## 12.1 Force Majeure

- 12.1.1 Any delays in or failure of performance by either Party under this Agreement will not be considered a breach of this Agreement and if and to the extent that such delay or failure is caused by occurrences beyond the reasonable control of that Party including acts of God; acts, regulations and laws of any government; strikes or other concerted acts of workers; fire; floods; explosions; riots; wars; rebellion; and sabotage; and any time for performance hereunder will be extended by the actual time of delay caused by any such occurrence.
- 12.1.2 If either Party is prevented from carrying out its obligations:
  - (a) under this Agreement for a continuous period of [\*\*\*] ([\*\*\*]) months the other Party may terminate this Agreement on giving [\*\*\*] ([\*\*\*]) days prior written notice provided always that at the date upon which termination becomes effective the Party which was prevented from carrying out its obligations under this Agreement remains so prevented. The Terminating Party may, at its discretion, choose not to terminate any or all of the Licence Addendum notwithstanding termination of this Agreement, by specifying such in its notice when terminating this Agreement. The relevant terms of this Agreement shall continue in force thereafter to the extent necessary to give effect to the terms of any Licence Addendum(s) which are not terminating until the last such Licence Addendum either expires or is terminated.
  - (b) under any Licence Addendum for a continuous period of [\*\*\*] ([\*\*\*]) months the other Party may terminate the relevant Licence Addendum on giving [\*\*\*] ([\*\*\*]) days prior written notice provided always that at the date upon which termination becomes effective the Party which was prevented from carrying out its obligations under the relevant Licence Addendum remains so prevented.

## 12.2 Amendment

This Agreement may only be amended in writing signed by duly authorised representatives of UCLB and the Licensee.

# 12.3 Assignment and Third Party Rights

- 12.3.1 Subject to Clause 12.3.2, neither Party shall assign, mortgage, charge or otherwise transfer any rights or obligations under this Agreement, nor any of the rights under the Licensed Technology, without the prior written consent of the other Party.
- 12.3.2 UCLB may assign all its rights and obligations under this Agreement together with its rights in the Licensed Technology to any third party to which it transfers all or substantially all of its assets or business in the relevant Field, provided that the assignee undertakes to the Licensee to be bound by and perform the obligations of the assignor under this Agreement.

12.3.3 The Licensee, subject to obtaining the consent of UCLB which shall not be unreasonably withheld or delayed (except in relation to those categories of persons or Affiliates of persons prohibited by Clause 2.3), may assign all its rights and obligations under this Agreement together with its rights in the Licensed Technology to any third party to which it transfers all or substantially all of its assets or business, provided that the assignee undertakes to UCLB to be bound by and perform the obligations of the assignor under this Agreement. However the Licensee shall not have such a right to assign this Agreement if it is insolvent..

#### 12.4 Waiver

Any waiver given under or in relation to this Agreement shall be in writing and signed by or on behalf of the relevant Party. No failure or delay on the part of either Party to exercise any right or remedy under this Agreement shall be construed or operate as a waiver thereof, nor shall any single or partial exercise of any right or remedy preclude the further exercise of such right or remedy.

## 12.5 Invalid Clauses

If any provision or part of this Agreement is held to be invalid, amendments to this Agreement may be made by the addition or deletion of wording as appropriate to remove the invalid part or provision but otherwise retain the provision and the other provisions of this Agreement to the maximum extent permissible under applicable law.

### 12.6 No Agency

Neither Party shall act or describe itself as the agent of the other, nor shall it make or represent that it has authority to make any commitments on the other's behalf.

## 12.7 Interpretation

In this Agreement:

- 12.7.1 the headings are used for convenience only and shall not affect its interpretation;
- 12.7.2 references to persons shall include incorporated and unincorporated persons; references to the singular include the plural and vice versa; and references to the masculine include the feminine;
- 12.7.3 references to Clauses and Schedules mean clauses of, and schedules to, this Agreement;
- 12.7.4 references in this Agreement to termination shall include termination by expiry;

- 12.7.5 where the word "including" is used it shall be understood as meaning "including without limitation";
- 12.7.6 any reference to any English law term for any action, remedy, method or judicial proceeding, legal document, legal status, court, official or any legal concept or thing shall in respect of any jurisdiction other than England be deemed to include what most nearly approximates in that jurisdiction to the English law term;
- 12.7.7 where there is any conflict or inconsistency between the main body of this agreement and any of the schedules, then the main body of the agreement shall prevail;
- 12.7.8 where there is any conflict or inconsistency between the main body of this agreement together with the schedules and any Licence Addendum then the terms of main body of this agreement together with the schedules shall prevail unless expressly stated otherwise in the relevant Licence Addendum;
- 12.7.9 time shall be of the essence in relation to the performance of the Licensee's obligations under this Agreement; and
- 12.7.10 any reference to the sale of a Licensed Product by the Licensee or its Affiliates or Sub-licensees will be taken to include any supply or other disposal of Licensed Products, and the term sold shall be construed accordingly.

## 12.8 Notices. Addresses for Service

- 12.8.1 Any notice to be given under this Agreement shall be in English, in writing and shall be delivered by first class recorded delivery mail (if sent to an inland address) or by international courier (if sent to an address outside of the United Kingdom), to the address of the relevant Party set out at the head of this Agreement, or such other address as that Party may from time to time notify to the other Party in accordance with this Clause 12.8.
- 12.8.2 Notices sent as above shall be deemed to have been received one (1) working day after the day of posting in the case of delivery inland first class recorded delivery mail, or three (3) working days after the date of collection by the international courier.

### 12.9 Law and Jurisdiction

The validity, construction and performance of this Agreement, and any contractual and non-contractual claims arising hereunder, shall be governed by English law and shall be subject to the exclusive jurisdiction of the English courts to which the parties hereby submit, except that a Party may seek an interim injunction (or an equivalent remedy) in any court of competent jurisdiction.

## 12.10 Entire Agreement

This Agreement, including its Schedules, sets out the entire agreement between the Parties relating to its subject matter and supersedes all prior oral or written agreements, arrangements or understandings between them relating to such subject matter. Subject to Clause 10.7.5, the Parties acknowledge that they are not relying on any representation, agreement, term or condition which is not set out in this Agreement.

## 12.11 Third Parties

Except for the rights of UCL as provided in Clause 2.4, the rights of the Indemnitees as provided in Clause 10.6 and the limitations of liability afforded to the Indemnitees pursuant to Clause 10.7, who may in their own right enforce and rely on the provisions of those Clauses, this Agreement does not create any right enforceable by any person who is not a party to it ("Third Party") under the Contracts (Rights of Third Parties) Act 1999, but this Clause does not affect any right or remedy of a Third Party which exists or is available apart from that Act. The Parties may amend, renew, terminate or otherwise vary all or any of the provisions of this Agreement, including Clauses 2.4, 10.6 and 10.7, without the consent of UCL and/or the Indemnitees.

## 12.12 Non-use of Names; Announcements

- 12.12.1 The Licensee shall not use, and shall ensure that its Affiliates and Sub-licensees do not use, the name, any adaptation of the name, any logo, trademark or other device of UCLB, nor of the inventors named on the Patents nor the Principal Investigators in any advertising, promotional or sales materials without prior written consent obtained from UCLB in each case, except that the Licensee may state that it is licensed by UCLB under the Patents.
- 12.12.2 Except as permitted under Clause 6.7, neither Party shall make any press or other public announcement concerning any aspect of this Agreement, or make any use of the name or trade marks of the other Party in connection with or in consequence of this Agreement, without the prior written consent of the other Party.

#### 12.13 Escalation

If the Parties are unable to reach agreement on any issue concerning this Agreement or the Project within [\*\*\*] days after one Party has notified the other of that issue, they will refer the matter to the [\*\*\*] in the case of UCLB, and to the [\*\*\*] in the case of the Licensee in an attempt to resolve the issue within the time specified in this Agreement in the case of other disputes. Either Party may bring proceedings in accordance with Clause 12.9 if the matter has not been resolved within that 14 day or such other period as prescribed, and either Party may apply to the court for an injunction, whether or not any issue has been escalated under this clause.

# **EXECUTED** on the date set out at the head of this Agreement.

For and on behalf of UCL Business PLC	For and on behalf of Athena Vision Ltd	
/s/ Anne Lane	/s/ Rachel Hemsley	
Signed	Signed	
Anne Lane	Rachel Hemsley	
Print name	Print name	
Executive Director UCL Business PLC	Director	
Title	Title	
04/02/2015	04 February 2015	
Date	Date	

## **SCHEDULE 1**

## TEMPLATE LICENCE ADDENDUM

LICENCE ADDENDUM NUMBER: [ ]	
TITLE OF TECHNOLOGY LICENSED: [ ]	

### **BETWEEN:**

DATED: [ ]

- (1) UCL BUSINESS PLC, whose registered office is The Network Building, 97 Tottenham Court Road, London W1T 4TP ("UCLB");
- (2) **ATHENA VISION LTD**, a company incorporated in England and Wales under company registration number 09348737 whose principal place of business is at c/o UCL Business PLC, The Network Building, 97 Tottenham Court Road, London W1T 4TP United Kingdom (the "Licensee").

### WHEREAS:

- A. University College London ("UCL"), through the Founders, has developed certain technology and owns certain intellectual property rights relating to the Licensed Technology.
- B. UCL has assigned to UCLB all of its right, title and interest in and to such property.
- C. UCLB and the Licensee entered into an exclusive licence agreement dated 4 February 2015 (the "Licence Agreement") to govern the terms under which the Licensed Technology will be licensed to the Licensee, subject to the Licensee and UCLB entering into this Licence Addendum in respect of the relevant Licensed Technology.

## NOW IT IS AGREED as follows:

- 1. Interpretation
- 1.1 The terms of the Licence Agreement apply to this Licence Addendum.
- 1.2 Defined terms used in the Licence Agreement shall have the same meaning when used herein.
- 1.3 In the case of a conflict between this Licence Addendum and the Licence Agreement, the terms of the Licence Agreement shall prevail unless expressly stated otherwise in this Licence Addendum.

# 2. Effective Date

The effective date of this Licence Addendum shall be the same as the Commencement Date of the Licence Agreement (the "Effective Date").

- 3. Payments
- 3.1 The payments are as specified in Clause 5 of the Licence Agreement.
- 4. Current Development Plan

The Current Development Plan for the Licensed Technology is shown below and shall be subject to Clause 6.3 of the License Agreement.

Activity
Preclin/manufacture
Initiate Phase I/II
Initiate Phase II/III
BLA submission

Timeline

## 5. Law and Jurisdiction.

5.1 The validity, construction and performance of this Licence Addendum, and any contractual and non-contractual claims arising hereunder, shall be governed by English law and shall be subject to the exclusive jurisdiction of the English courts to which the parties hereby submit, except that a Party may seek an interim injunction (or an equivalent remedy) in any court of competent jurisdiction.

**EXECUTED** on the date set out at the head of this Licence Addendum.

For and on behalf of UCL Business PLC	For and on behalf of Athena Vision Ltd	
Signed	Signed	
Print name	Print name	
Title	Title	
Date	Date	

# Licence Addendum Number [x]: Appendix 1

# Part A - The Licenced Technology

The Patents [insert]

**The Know-how** [Note – Know-how should be described and any key documents listed.

For example this may include:

• copies of relevant lab notebooks

· written research reports

technical dossiers

• databases of test results]

[other] [insert any other licensed technology info here—e.g. data sets, databases,

software etc]

Principal Investigator [insert]

Field [insert]

**Territory** [insert]

[Part B - Disclosures]

[Appendix 2]

# [List of Countries and Territories of the Patents]

## **SCHEDULE 2**

## APPOINTMENT OF EXPERT

If either Party wishes to appoint an independent expert (the "Expert") to determine any matter pursuant to any Clause of this Agreement, the following procedures will apply:

- 1. The Party wishing to appoint the Expert ("the Appointing Party") will serve a written notice on the other Party ("the Responding Party"). The written notice will specify the Clause pursuant to which the appointment is to be made and will contain reasonable details of the matter(s) which the Appointing Party wishes to refer to the Expert for determination
- 6. The Parties shall within [\*\*\*] ([\*\*\*]) days following the date of the Appointing Party's written notice use all reasonable efforts to agree who is to be appointed as the Expert to determine the relevant matter(s). If the Parties are unable to agree upon the identity of the Expert within that timescale, the Expert shall be appointed by the President (for the time being) of the Licensing Executives Society Britain and Ireland upon written request of either Party.
- 7. Each Party will within [\*\*\*] ([\*\*\*]) days following appointment of the Expert, prepare and submit to the Expert and the other Party a detailed written statement setting out its position on the matter(s) in question and including any proposals which it may wish to make for settlement or resolution of the relevant matter.
- 8. Each Party will have [\*\*\*] ([\*\*\*]) days following receipt of the other Party's written statement to respond in writing thereto. Any such response will be submitted to the other Party and the Expert.
- 9. The Expert will if he/she deems appropriate be entitled to seek clarification from the Parties as to any of the statements or proposals made by either Party in their written statement or responses. Each Party will on request make available all information in its possession and shall give such assistance to the Expert as may be reasonably necessary to permit the Expert to make his/ her determination.
- 10. The Expert will issue his/ her decision on the matter(s) referred to him/ her in writing as soon as reasonably possible, but at latest within [\*\*\*] ([\*\*\*]) months following the date of his/ her appointment. The Expert's decision shall (except in the case of manifest error) be final and binding on the Parties.
- 11. The Expert will at all times act as an independent and impartial expert and not as an arbitrator.
- 12. The Expert's charges will be borne as he/ she determines in his written decision.

# **SCHEDULE 3**

# **DEFINITION OF TOBACCO INDUSTRY FUNDING (REVISED 2009)**

FROM THE CANCER RESEARCH UK CODE OF PRACTICE ON TOBACCO INDUSTRY FUNDING TO UNIVERSITIES. <a href="http://www.cancerresearchuk.org/science/funding/terms-conditions/funding-policies/policy-tobacco/">http://www.cancerresearchuk.org/science/funding/terms-conditions/funding-policies/policy-tobacco/</a>

A tobacco company is defined for the purposes of this policy as one that:

- Derives over 5% of revenues from manufacturing tobacco products;
- Derives 15%+ of revenues from the manufacture of products necessary for the production of tobacco products;
- Derives 15% of revenues from the sale of tobacco products (and has 30 or more staff);
- Owns a tobacco company (the company owns 50% or more of a tobacco company);
- Is more than 50% owned by a company with tobacco involvement.

The following do not constitute tobacco industry funding for the purposes of this Code:

- legacies from tobacco industry investments (provided these are sold on immediately)
- funding from a trust or foundation no longer having any connection with the tobacco industry even though it may bear a name that (for historical reasons) has tobacco industry associations.

## LICENCE ADDENDUM NUMBER 1

## TITLE OF TECHNOLOGY LICENSED: [\*\*\*]

DATED: 4 February 2015

### **BETWEEN:**

- (1) **UCL BUSINESS PLC**, whose registered office is The Network Building, 97 Tottenham Court Road, London W1T 4TP ("UCLB"); and
- (2) **ATHENA VISION LTD**, a company incorporated in England and Wales under company registration number 09348737 whose principal place of business is at c/o UCL Business PLC, The Network Building, 97 Tottenham Court Road, London W1T 4TP United Kingdom (the "Licensee").

### WHEREAS:

- A. University College London ("UCL"), through the Founders, has developed certain technology and owns certain intellectual property rights relating to the Licensed Technology.
- B. UCL has assigned to UCLB all of its right, title and interest in and to such property.
- C. UCLB and the Licensee entered into an exclusive licence agreement dated 4 February 2015 (the "Licence Agreement") to govern the terms under which the Licensed Technology will be licensed to the Licensee, subject to the Licensee and UCLB entering into this Licence Addendum in respect of the relevant Licensed Technology.

# NOW IT IS AGREED as follows:

- 1. Interpretation
- 1.1 The terms of the Licence Agreement apply to this Licence Addendum.
- 1.2 Defined terms used in the Licence Agreement shall have the same meaning when used herein.
- 1.3 In the case of a conflict between this Licence Addendum and the Licence Agreement, the terms of the Multiple Licence Agreement shall prevail unless expressly stated otherwise in this Licence Addendum.
- 2. Effective Date

The effective date of this Licence Addendum shall be the same as the Commencement Date of the Licence Agreement (the "Effective Date").

# 3. **Payments**

The payments are as specified in Clause 5 of the Licence Agreement.

# 4. Current Development Plan

The Current Development Plan for the Licensed Technology is shown below and shall be subject to Clause 6.3 of the License Agreement

Activity	Timeline
Preclin/manufacture	[***]
Initiate Phase I/II	[***]
Initiate Phase II/III	[***]
BLA submission	[***]

# 5. Law and Jurisdiction.

The validity, construction and performance of this Licence Addendum, and any contractual and non-contractual claims arising hereunder, shall be governed by English law and shall be subject to the exclusive jurisdiction of the English courts to which the parties hereby submit, except that a Party may seek an interim injunction (or an equivalent remedy) in any court of competent jurisdiction.

**EXECUTED** on the date set out at the head of this Licence Addendum.

For and on behalf of UCL Business PLC	For and on behalf of <b>Athena Vision Ltd</b>	
/s/ Anne Lane	/s/ Rachel Hemsley	
Signed	Signed	
Anne Lane	Rachel Hemsley	
Print name	Print name	
Executive Director UCL Business PLC	Director	
Title	Title	
04/02/2015	04 February 2015	
Date	Date	

# Licence Addendum Number 1: Appendix 1

# Part A – The Licenced Technology

The Patents [\*\*\*]
The Know-how
The Know-how Data
[\*\*\*]
Founders [\*\*\*]

FieldAs in the Licence AgreementTerritoryAs in the Licence Agreement

# Part B - Disclosures

[\*\*\*]

# Licence Addendum Number 1: Appendix 2

# **List of Countries and Territories of the Patents**

[\*\*\*]

## LICENCE ADDENDUM NUMBER 2

# TITLE OF TECHNOLOGY LICENSED: [\*\*\*]

DATED: 4 February 2015

## **BETWEEN:**

- (1) **UCL BUSINESS PLC**, whose registered office is The Network Building, 97 Tottenham Court Road, London W1T 4TP ("UCLB");
- (2) **ATHENA VISION LTD**, a company incorporated in England and Wales under company registration number 09348737 whose principal place of business is at c/o UCL Business PLC, The Network Building, 97 Tottenham Court Road, London W1T 4TP United Kingdom (the "Licensee").

## WHEREAS:

- A. University College London ("UCL"), through the Founders, has developed certain technology and owns certain intellectual property rights relating to the Licensed Technology.
- B. UCL has assigned to UCLB all of its right, title and interest in and to such property,
- C. UCLB and the Licensee entered into an exclusive licence agreement dated 4 February 2015 (the "Licence Agreement") to govern the terms under which the Licensed Technology will be licensed to the Licensee, subject to the Licensee and UCLB entering into this Licence Addendum in respect of the relevant Licensed Technology.

## NOW IT IS AGREED as follows:

- 1. Interpretation
- 1.1 The terms of the Licence Agreement apply to this Licence Addendum.
- 1.2 Defined terms used in the Licence Agreement shall have the same meaning when used herein.
- 1.3 In the case of a conflict between this Licence Addendum and the Licence Agreement, the terms of the Licence Agreement shall prevail unless expressly stated otherwise in this Licence Addendum.
- 2. Effective Date

The effective date of this Licence Addendum shall be the same as the Commencement Date of the Licence Agreement (the "Effective Date").

# 3. **Payments**

The payments are as specified in Clause 5 of the Licence Agreement.

# 4. Current Development Plan

The Current Development Plan for the Licensed Technology is shown below and shall be subject to Clause 6.3 of the License Agreement.

Activity	Timeline
Preclin/manufacture	[***]
Initiate Phase I/II	[***]
Initiate Phase II/III	[***]
BLA submission	[***]

## 5. Law and Jurisdiction.

5.1 The validity, construction and performance of this Licence Addendum, and any contractual and non-contractual claims arising hereunder, shall be governed by English law and shall be subject to the exclusive jurisdiction of the English courts to which the parties hereby submit, except that a Party may seek an interim injunction (or an equivalent remedy) in any court of competent jurisdiction.

**EXECUTED** on the date set out at the head of this Licence Addendum.

For and on behalf of UCL Business PLC	For and on behalf of  Athena Vision Ltd	
/s/ Anne Lane	/s/ Rachel Hemsley	
Signed	Signed	
Anne Lane	Rachel Hemsley	
Print name	Print name	
Executive Director UCL Business PLC	Director	
Title	Title	
04/02/2015	04 February 2015	
Date	Date	

# Licence Addendum Number 2: Appendix 1

# Part A – The Licenced Technology

The Patents [\*\*\*]
The Know-how
The Know-how Data
[\*\*\*]
Founders
[\*\*\*]

FieldAs in the Licence AgreementTerritoryAs in the Licence Agreement

# Part B - Disclosures

[\*\*\*]

# Licence Addendum Number 2: Appendix 2

# **List of Countries and Territories of the Patents**

[\*\*\*]

## LICENCE ADDENDUM NUMBER 3

# TITLE OF TECHNOLOGY LICENSED: [\*\*\*]

DATED: 4 February 2015

## **BETWEEN:**

- (1) **UCL BUSINESS PLC**, whose registered office is The Network Building, 97 Tottenham Court Road, London W1T 4TP ("UCLB");
- (2) **ATHENA VISION LTD**, a company incorporated in England and Wales under company registration number 09348737 whose principal place of business is at c/o UCL Business PLC, The Network Building, 97 Tottenham Court Road, London W1T 4TP United Kingdom (the "Licensee").

## WHEREAS:

- A. University College London ("UCL"), through the Founders, has developed certain technology and owns certain intellectual property rights relating to the Licensed Technology.
- B. UCL has assigned to UCLB all of its right, title and interest in and to such property.
- C. UCLB and the Licensee entered into an exclusive licence agreement dated 4 February 2015 (the "Licence Agreement") to govern the terms under which the Licensed Technology will be licensed to the Licensee, subject to the Licensee and UCLB entering into this Licence Addendum in respect of the relevant Licensed Technology.

## NOW IT IS AGREED as follows:

- 1. Interpretation
- 1.1 The terms of the Licence Agreement apply to this Licence Addendum.
- 1.2 Defined terms used in the Licence Agreement shall have the same meaning when used herein.
- 1.3 In the case of a conflict between this Licence Addendum and the Licence Agreement, the terms of the Licence Agreement shall prevail unless expressly stated otherwise in this Licence Addendum.
- 2. Effective Date

The effective date of this Licence Addendum shall be the same as the Commencement Date of the Licence Agreement (the "Effective Date").

# 3. **Payments**

The payments are as specified in Clause 5 of the Licence Agreement.

# 4. Current Development Plan

The Current Development Plan for the Licensed Technology is shown below and shall be subject to Clause 6.3 of the License Agreement.

Activity	Timeline
Preclin/manufacture	[***]
Initiate Phase I/II	[***]
Initiate Phase II/III	[***]
BLA submission	[***]

## 5. Law and Jurisdiction

5.1 The validity, construction and performance of this Licence Addendum, and any contractual and non-contractual claims arising hereunder, shall be governed by English law and shall be subject to the exclusive jurisdiction of the English courts to which the parties hereby submit, except that a Party may seek an interim injunction (or an equivalent remedy) in any court of competent jurisdiction.

**EXECUTED** on the date set out at the head of this Licence Addendum.

For and on behalf of UCL Business PLC	For and on behalf of <b>Athena Vision Ltd</b>	
/s/ Anne Lane	/s/ Rachel Hemsley	
Signed	Signed	
Anne Lane	Rachel Hemsley	
Print name	Print name	
Executive Director UCL Business PLC	Director	
Title	Title	
04/02/2015	04 February 2015	
Date	Date	

# Licence Addendum Number 3: Appendix 1

# Part A – The Licenced Technology

The Patents [\*\*\*]
The Know-how [\*\*\*]
Founders [\*\*\*]

FieldAs in the Licence AgreementTerritoryAs in the Licence Agreement

# Part B – Disclosures

[\*\*\*]

# Licence Addendum Number 3: Appendix 2

# **List of Countries and Territories of the Patents**

[\*\*\*]

LICENCE ADDENDUM NUMBER: 5

TITLE OF TECHNOLOGY LICENSED: [\*\*\*]

DATED: 15 December 2017

#### **BETWEEN:**

(1) **UCL BUSINESS PLC**, whose registered office is The Network Building, 97 Tottenham Court Road, London W1T 4TP ("**UCLB**");

and

(2) **MEIRAGTX LIMITED (FORMERLY KADMON GENE THERAPY HOLDINGS LIMITED)**, a company incorporated in England and Wales with registered number 9501998 and having its registered office at c/o Legalinx Ltd, 1 Fetter Lane, London EC4A 1BR ("**Meira**").

#### WHEREAS:

- A. University College London ("UCL"), through the Founders, has developed certain technology and owns certain intellectual property rights relating to the Licensed Technology.
- B. UCL has assigned to UCLB all of its right, title and interest in and to such property.
- C. UCLB and Athena Vision Ltd ("Athena") were party to a Licence Agreement dated 4 February 2015, as amended by Amendment No. 1 to Exclusive Licence Agreement, effective as of 27 March 2015, and Amendment No. 2 to Exclusive Licence Agreement effective as of 28 July 2017, by and between UCLB and Athena, and any subsequent amendments, supplements, addendums or modifications thereto or restatements thereof, under which UCLB licensed to Athena certain technology and intellectual property relating to ocular gene therapy, which UCLB acquired by assignment from University College London, for development and commercialization by Athena (the "Licence").
- D. Athena and Meira entered into a Collaboration, Development and Licence Agreement dated 27 April 2015 (the "CDLA") under which Meira and Athena agreed to collaborate on the research, development and commercialisation of the intellectual property licensed to Athena by UCLB under the Licence.
- E. Subject to the terms and conditions set forth in a Share for Share Exchange Deed between Athena, UCLB, the Founders (as defined therein), [\*\*\*] and Meira (the "Share Exchange Deed"), the CDLA was terminated in accordance with clause 12.1(a) of the CDLA.
- F. UCLB, Athena and Meira agreed to novate Athena's rights, obligations and liabilities under the Licence to Meira on the terms of this Deed of Novation and Amendment with effect from Completion (as defined in the Share Exchange Deed) (the "**Effective Date**").
- G. UCLB now wishes to grant and Meira wishes to accept a licence to the Specified Technology ([\*\*\*]), subject to UCLB and Meira entering into this Licence Addendum in respect of this Specified Technology. The Parties have agreed that this Specified Technology will be licensed to Meira through this Licence Addendum and under the terms of the Licence as modified herein.

#### NOW IT IS AGREED as follows:

# 1. Interpretation

- 1.1 The terms of the Licence apply to this Licence Addendum.
- 1.2 Defined terms used in the Licence shall have the same meaning when used herein.
- 1.3 In the case of a conflict between this Licence Addendum and the Licence, the terms of the Licence shall prevail unless expressly stated otherwise in this Licence Addendum.

#### 2. Effective Date

The effective date of this Licence Addendum shall be the same as the Commencement Date of the Licence (the "Effective Date").

#### Payments

The consideration for this licence is as specified in Clause 5 of the Licence. This Clause 5 covers the developmental milestone, cumulative sales milestone and royalty on Net Sales Value payment for the specified technology [\*\*\*]. In addition to the payments detailed in Clause 5 of the Licence, Meira shall [\*\*\*].

# 4. Special Terms

The Parties hereby specifically agree that Clause 5 of this Licence Addendum shall prevail over any conflicting provisions of the Licence.

## 5. Updated Initial Development Plan

The updated Initial Development Plan for the Licensed Technology is shown below and shall be subject to Clause 6.3 of the Licence.

Activity	Timeline
Phase I/II Start	[***]
Phase I/II Finish	[***]
Phase III /pivotal confirmatory study Start	[***]
Phase III /pivotal confirmatory study Finish	[***]

## 6. Law and Jurisdiction.

6.1 The validity, construction and performance of this Licence Addendum, and any contractual and non-contractual claims arising hereunder, shall be governed by English law and shall be subject to the exclusive jurisdiction of the English courts to which the Parties hereby submit, except that a Party may seek an interim injunction (or an equivalent remedy) in any court of competent jurisdiction.

**EXECUTED** on the date set out at the head of this Licence Addendum.

For and on behalf of UCL Business PLC	For and on behalf of <b>MEIRAGTX Limited</b>	
/s/ Anne Lane	/s/ Richard Giroux	
Signed	Signed	
Anne Lane	Rich Giroux	
Print name	Print name	
Executive Director	Chief Operating Officer	
Title	Title	
18/12/17	12.18.17	
Date	Date	

# Licence Addendum Number 5: Schedule 1 Licensed Technology

Part A – The Patents
[***]

Part B - The Know-how

[\*\*\*]

Part C - The Materials

[\*\*\*]

# Schedule 2

# **List of Countries and Territories for Patents**

[\*\*\*]

# AMENDMENT NO. 1 TO EXCLUSIVE LICENCE AGREEMENT

THIS AMENDMENT NO. 1 TO EXCLUSIVE LICENCE AGREEMENT (this "Amendment"), effective as of March 27, 2015 (the "Amendment Effective Date"), is entered into by and between Athena Vision Ltd, a company incorporated in England and Wales under company registration number 09348737 whose principal place of business is at c/o UCL Business PLC, The Network Building, 97 Tottenham Court Road, London W1T 4TP United Kingdom ("UCLB") and UCL Business PLC, whose registered office is The Network Building, 97 Tottenham Court Road, London W1T 4TP United Kingdom ("UCLB"). The Licensee and UCLB are each sometimes referred to herein as a "Party" and collectively referred to herein as the "Parties".

#### WITNESSETH:

**WHEREAS**, the Parties entered into an Exclusive Licence Agreement dated as of 4<sup>th</sup> February, 2015 pursuant to which the Licensee is developing and commercializing Licensed Products (the "**Agreement**");

WHEREAS, the Parties mutually desire to further amend the Agreement on the terms and conditions set forth in this Amendment.

**NOW**, **THEREFORE**, in consideration of the foregoing statements and the mutual agreements and covenants herein contained, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

- 1. **Definitions and References**. Except as set forth herein, capitalized terms not otherwise defined or amended in this Amendment shall have the meaning ascribed to them in the Agreement, as amended by this Amendment. References to Articles, Sections or Schedules are to the same with all their subparts as they appear in the Agreement. References to Paragraphs are to the numbered paragraphs with all their subparts as they appear in this Amendment.
  - 2. Amendment to the Agreement. Effective as of the Amendment Effective Date, the Agreement shall be amended as set forth in this Paragraph 2:
- a) Licence Addendum No. 3 shall be replaced in its entirety by the Licence Addendum No. 3 appended hereto.

#### 3. Warranties.

Each Party hereby warrants to the other Party as follows:

- (i) it has the full corporate power and authority to enter into and deliver this Amendment and to perform and consummate the transactions contemplated hereby;
- (ii) all corporate acts and other proceedings required to be taken to authorize such execution, delivery, and consummation have been duly and properly taken and obtained;

- (iii) this Amendment has been duly executed and delivered by such Party and constitutes a legal, valid and binding obligation of such Party, enforceable against such Party in accordance with its terms, except as such enforceability may be limited by applicable insolvency and other laws affecting creditors' rights generally or by the availability of equitable remedies; and
- (iv) except as expressly amended by this Amendment the Agreement is in full force and effect in accordance with its terms and, to each Party's knowledge, there exist no breaches, defaults or events which would (with the giving of notice, the passage of time or both) give rise to a breach, default or other right to terminate or modify the Agreement.

#### 4. Other.

- (a) **Effect of Amendment**. From and after the Amendment Effective Date, all references to the Agreement shall mean the Agreement as amended by this Amendment.
- (b) **Counterparts**. This Amendment may be executed in two or more counterparts, each of which shall be deemed an original but all of which together shall constitute one and the same instrument. Signatures to this Amendment transmitted by fax, by email in "portable document format" (".pdf") or by any other electronic means intended to preserve the original graphic and pictorial appearance of this Amendment shall have the same effect as physical delivery of the paper document bearing original signature.
- (c) **Entire Amendment**. This Amendment contains the entire understanding of the Parties with respect to the subject matter of this Amendment. Except as specifically modified and amended hereby, all of the terms, provisions, requirements and specifications contained in the Agreement remain in full force and effect. Except as otherwise expressly provided herein, the Parties do not intend to, and the execution of this Amendment shall not, in any manner impair the Agreement, the purpose of this Amendment being simply to amend certain specific provisions of the Agreement only and to confirm and carry forward the Agreement, as hereby amended, in full force and effect. This Amendment may be amended, or any term hereof modified, only by a written instrument executed by both the Parties.
- (d) **Notices**. All notices, requests and other communications hereunder shall be in writing and shall be personally delivered or sent by fax transmission (and promptly confirmed by personal delivery, registered or certified mail or overnight courier) or by registered or certified mail, return receipt requested, postage prepaid, or sent by internationally-recognized overnight courier, in each case to the respective address specified below, or such other address as may be specified in writing to the other party hereto:

if to The Licensee to:

Athena Vision Limited c/o UCL Business PLC, The Network Building, 97 Tottenham Court Road, London W1T 4TP United Kingdom

Attention: Managing Director

Fax No.: +44

if to UCLB to:

UCL Business PLC The Network Building 97 Tottenham Court Road London W1T 4TP United Kingdom Fax No. +44 (0) 20 76679 9838

IN WITNESS WHEREOF, the Parties have executed this Amendment as of the Amendment Effective Date.

#### **Athena Vision Limited**

By: /s/ Stuart Naylor
Name: Stuart Naylor
Title: CEO

# **UCL Business PLC**

By: /s/ Anne Lane
Name: Anne Lane
Title: Executive Director

## LICENCE ADDENDUM NUMBER 3

## TITLE OF TECHNOLOGY LICENSED: [\*\*\*]

**DATED: March 27, 2015** 

#### **BETWEEN:**

- (1) **UCL BUSINESS PLC**, whose registered office is The Network Building, 97 Tottenham Court Road, London W1T 4TP ("UCLB"); and
- (2) **ATHENA VISION LTD**, a company incorporated in England and Wales under company registration number 09348737 whose principal place of business is at c/o UCL Business PLC, The Network Building, 97 Tottenham Court Road, London W1T 4TP United Kingdom (the "Licensee").

#### WHEREAS:

- A. University College London ("UCL"), through the Founders, has developed certain technology and owns certain intellectual property rights relating to the Licensed Technology.
- B. UCL has assigned to UCLB all of its right, title and interest in and to such property.
- C. UCLB and the Licensee entered into an exclusive licence agreement dated 4<sup>th</sup> February 2015 (the "Licence Agreement") to govern the terms under which the Licensed Technology will be licensed to the Licensee, subject to the Licensee and UCLB entering into this Licence Addendum in respect of the relevant Licensed Technology.

# NOW IT IS AGREED as follows:

#### 1. Interpretation

- 1.1 The terms of the Licence Agreement apply to this Licence Addendum.
- 1.2 Defined terms used in the Licence Agreement shall have the same meaning when used herein.
- 1.3 In the case of a conflict between this Licence Addendum and the Licence Agreement, the terms of the Licence Agreement shall prevail unless expressly stated otherwise in this Licence Addendum.

#### 2. Effective Date

The effective date of this Licence Addendum shall be the same as the Commencement Date of the Licence Agreement (the "Effective Date").

# 3. Payments

The payments are as specified in Clause 4 of the Licence Agreement.

# 4. Current Development Plan

The Current Development Plan for the Licensed Technology is shown below and shall be subject to Clause 6.3 of the License Agreement.

Activity	Timeline
Preclin/manufacture	[***]
Initiate Phase I/II	[***]
Initiate Phase II/III	[***]
BLA submission	[***]

## 5. Law and Jurisdiction.

5.1 The validity, construction and performance of this Licence Addendum, and any contractual and non-contractual claims arising hereunder, shall be governed by English law and shall be subject to the exclusive jurisdiction of the English courts to which the parties hereby submit, except that a Parry may seek an interim injunction (or an equivalent remedy) in any court of competent jurisdiction.

**EXECUTED** on the date set out at the head of this Licence Addendum.

For and on behalf of	For and on behalf of	
UCL Business PLC	Athena Vision Ltd	
/s/ Anne Lane	/s/ Stuart Naylor	
Signed	Signed	
Anne Lane	Stuart Naylor	
Print name	Print name	
Executive Director	CEO	
Title	Title	
27/3/15	27-3-15	
Date	Date	

# Licence Addendum Number 3: Appendix 1

# Part A – The Licenced Technology

The Patents [\*\*\*]
The Know-how [\*\*\*]
[other] [\*\*\*]
Founders [\*\*\*]

FieldAs in the Licence AgreementTerritoryAs in the Licence Agreement

# [Part B - Disclosures]

# Appendix 2

# **List of Countries and Territories of the Patents**

[\*\*\*

# **AMENDMENT NO. 2 TO EXCLUSIVE LICENCE AGREEMENT**

This AMENDMENT NO. 2 TO EXCLUSIVE LICENSE AGREEMENT (this "Amendment"), effective as of July 28, 2017 (the "Amendment Effective Date"), is entered into by and between MeiraGTx Limited, having a place of business located at 92 Britannia Walk, London N1 7NQ United Kingdom ("MeiraGTx") and UCL Business PLC, whose registered office is The Network Building, 97 Tottenham Court Road, London W1T 4TP United Kingdom ("UCLB"). MeiraGTx and UCLB are each sometimes referred to herein as a "Party" and collectively referred to herein as the "Parties".

#### WITNESSETH:

WHEREAS, UCLB and Athena Vision Ltd., a company incorporated under the laws of England and Wales under company registration number 09348737 ("Athena") entered into a Licence Agreement dated 4 February 2015, as amended by Amendment No. 1 to Exclusive Licence Agreement, effective as of 27 March 2015 (as amended, the "Licence Agreement"), pursuant to which UCLB licensed to Athena certain technology and intellectual property relating to ocular gene therapy, which UCLB acquired by assignment from University College London, for development and commercialization by Athena.

**WHEREAS**, pursuant to a Share for Share Exchange Deed made and delivered in 2016 by and among [\*\*\*] (collectively, the "**Transferring Shareholders**"), Athena, and MeiraGTx (the "**Exchange Deed**"), the Transferring Shareholders agreed to sell to MeiraGTx a total of [\*\*\*] each in the capital of Athena (the "**Shares**") in exchange for a certain number of shares of MeiraGTx on the terms and conditions of the Exchange Deed.

**WHEREAS,** upon the completion of the sale and purchase of the Shares in accordance with Clause 5 of the Exchange Deed occurring on or about April of 2016 (the "Completion"), MeiraGTx increased its shareholding in Athena from 60% to 100% and Athena became a wholly-owned subsidiary of MeiraGTx.

**WHEREAS,** UCLB, Athena, and MeiraGTx entered into a Deed of Novation and Amendment in 2016 ("**Deed of Novation and Amendment**") pursuant to which the parties thereto agreed to, among other things, novate Athena's rights, obligations, and liabilities under the Licence Agreement to MeiraGTx on the terms and conditions of the Deed of Novation and Amendment (the "**Novation**").

**WHEREAS**, the Novation became effective as of the Completion, the Parties now mutually desire to further amend the Licence Agreement on the terms and conditions set forth in this Amendment.

**NOW THEREFORE**, in consideration of the foregoing statements and the mutual agreements and covenants herein contained, and for other good an valuable consideration, the sufficiency of which are hereby acknowledged, the Parties hereby agree as follows.

1. **Definitions**. Except as set forth herein, capitalized terms not otherwise defined or amended in this Amendment shall have the meaning ascribed to them in the Licence Agreement, as amended by this Amendment. References to Articles, Clauses, or Schedules are to the same with all their subparts as they appear in the Licence Agreement. References to Sections are to the numbered paragraphs with all their subparts as they appear in this Amendment.

- 2. **Amendment to the Agreement**. Effective as of the Amendment Effective Date, the Agreement shall be and is hereby amended as set forth in this Section 2:
  - (a) The definition of "First Commercial Sale" is added to Clause 1.1 of the Licence Agreement as follows:
  - "First Commercial Sale means the first sale to a third party of a Licensed Product in a given regulatory jurisdiction after all regulatory and marketing approvals have been obtained for such Licensed Product in such jurisdiction. A sale shall not be deemed to have occurred if a Licensed Product is provided pursuant to an early access or compassionate use;"
    - (b) The definition of "Licensed Products" as defined in Clause 1.1 of the Licence Agreement is hereby amended and restated as follows:
  - "Licensed Products means any and all products that are developed, manufactured, used, or sold by or on behalf of the Licensee or its Affiliates or Sub-licensees and which (a) are within (or are manufactured using a process described in) a Valid Claim of the Patents; and/or (b) incorporate, or their development or manufacture makes use of, any of the Know-how and/or the Materials;"
    - (c) The definition of "Net Receipts" as defined in Clause 1.1 of the Licence Agreement is hereby amended and restated as follows:
- "Net Receipts means in respect of the Licensed Products, subject to Clause 5.6, the amount of any up-front cash payments (excluding value added or other sales tax), received by the Licensee or its Affiliates, from the Sub-licensee for the sub-licensing (including the grant of any option over a sub-licence) of the Licensed Products, excluding any performance-based milestone (whether at the stage of development, marketing or otherwise), success, bonus, sub-licence maintenance and periodic (including annual) sub-licence payments, due under any sub-licence agreement, and further excluding the following:
- a) amounts paid for equity of Licensee, up to its fair market value;
- b) debt financing of Licensee by such Sub-licensee;
- c) payments or reimbursements for research, development or commercialization services that are undertaken by Licensee for products or services;
- d) payments or reimbursements to Licensee for Patent expenses related to products or services;

- e) payments for the supply of products or materials used in performance of services;
- f) amounts received by Licensee from a Sub-licensee in consideration for Intellectual Property rights that are not the Patents, Materials or Know-how;
- g) payments received in connection with sales of products (including without limitation Licensed Products); or
- h) payments on the sale or merger of Licensee.

For the avoidance of doubt, non-cash consideration shall not form Net Receipts until (i) the Licensee has received cash consideration from the use, exploitation, disposal or other realisation of such consideration, or (ii) termination of this Agreement, whichever occurs sooner. Any dividend or similar monetary consideration received in respect of such non-cash consideration shall form Net Receipts."

(d) The definition of "Net Sales Value" as defined in Clause 1.1 of the Licence Agreement is hereby amended and restated as follows:

"Net Sales Value means in respect of the Licensed Products after their First Commercial Sale:

- a) the gross amount received by the Licensee or its Affiliates or Sub-licensees in arm's length sales of Licensed Products for cash consideration; and/ or
- b) where the sale is not at arm's length and/ or is for or includes a non-cash consideration, or if Licensed Products used or subject to Clause 6.10 disposed of for free by the Licensee or its Affiliates the relevant open market price for the Licensed Product in the country or territory in which the sale, use or disposal takes place or if the relevant open market price is not ascertainable, a reasonable price, assessed on an arm's length basis therefor,

after deduction of all documented:

- normal trade discounts (including early payment discounts) actually granted and any credits actually given for rejected or returned Licensed Products;
- ii) costs of packaging, insurance, carriage and freight, provided in each case that the amounts are separately charged to the purchaser on the relevant invoice;
- iii) value added tax or other sales tax; and
- iv) import duties or similar applicable government levies charged to the purchaser on the relevant invoice.

Sales of Licensed Products between the Licensee and its Affiliates shall not be taken into account for the purposes of calculating "Net Sales Value" unless there is no subsequent sale to a third party in an arm's length transaction for a cash consideration;"

- (e) Clause 2.2 of the Licence Agreement is hereby amended and restated as follows:
- "2.2 UCLB shall at the Licensee's request and cost execute such formal licences as may be necessary to enable the Licensee to register the licences granted to it under this Agreement with the Patent Offices in the relevant Territory. Such formal licence will reflect the terms of this Agreement where possible and for the avoidance of doubt if there is a conflict in the terms of such formal licence and this Agreement, the terms of this Agreement shall prevail. The Licensee shall use reasonable efforts to ensure that this Agreement shall not form part of any public record, except where disclosure of the terms of this Agreement are required by applicable law, rule or regulation (including the rules or regulations of a stock exchange upon which the Licensee's shares are sold)."
  - (f) Clause 5.3 of the Licence Agreement is hereby amended and restated as follows:
- "5.3 **Other Milestone Payments** Within [\*\*\*] ([\*\*\*]) days following achievement of each of the following milestone events by Licensee, its Affiliates or Sub-licensees, the Licensee shall notify UCLB in writing that the relevant milestone event has been achieved, provide documentary evidence of such achievement as appropriate and pay to UCLB, within a period of [\*\*\*] days, the amount(s) set out next to such milestone event below:

Milestone Event	Amount to be paid
[***]	£[***]
[***]	£[***]

(g) Clause 5.4 of the Licence Agreement is hereby amended and restated as follows:

# **"**5.4 **Annual Management Fees**

On each date referred to in the following table, the Licensee shall pay to UCLB the annual management fee set out next to such date in the table.

<u>Date</u>	Amount to be paid
Upon each anniversary of the Commencement Date until [***]	£50,000

(h) Clause 5.5 of the Licence Agreement is hereby amended and restated as follows:

#### 5.5 **Sales Linked Milestone Payments**

Upon achievement of each of the sales linked milestones set out in the following table by the Licensee, its Affiliates or Sub-licensees, the Licensee shall notify UCLB in writing that the relevant sales linked milestone has been achieved, provide the relevant documentary evidence and pay to UCLB the amount(s) set out next to such event in the table:

Sales Linked Milestones	Amount to be paid
When Net Sales Value reaches £[***]	£[***]
On the next $\mathfrak{L}[***]$ of Net Sales Value (when sales cumulatively reach $\mathfrak{L}[***]$ )	£[***]
On the next £[***] of Net Sales Value (When sales cumulatively reach £ [***])	£[***]
On the next $\mathfrak{L}[***]$ of Net Sales Value (when sales cumulatively reach $\mathfrak{L}[***]$ )	£[***]
On the next $\mathfrak{L}[***]$ of Net Sales Value (when sales cumulatively reach $\mathfrak{L}[***]$ )	£[***]
On the next $\mathfrak{L}[***]$ of Net Sales Value (when sales cumulatively reach $\mathfrak{L}[***]$ )	£[***]

(i) Clause 5.6 of the Licence Agreement is hereby amended and restated as follows:

# **"5.6 Royalties on Net Sales**

For each Licensed Product in each country, the Licensee shall pay to UCLB a royalty of [\*\*\*] % ([\*\*\*] per cent) being a percentage of the Net Sales Value of all Licensed Products sold by Licensee, its Affiliates or Sub-licensees. The Licensee's obligations to pay such royalty for a given Licensed Product in a given country shall begin after the First Commercial Sale of such Licensed Product in such country and shall end on the earlier to occur of the following: (a) expiration of the last Valid Claim of a Patent claiming such Licensed Product in such country; or (b) the tenth (10th) anniversary of the date of such First Commercial Sale in such country."

(j) Clause 5.7 of the Licence Agreement is hereby amended and restated as follows:

#### "5.7 Royalties on Net Receipts

In the event that the Licensee receives an up-front payment from a Sub-licensee, and the up-front payment is also in consideration for Intellectual Property rights that are not the Patents, Materials or Know-how, then the Licensee shall allocate, at a commercially reasonable rate, the portion of the up-front payment that is in consideration for Intellectual Property rights that are the Patents, Materials and Know-how. With respect to such portion, Licensee shall pay to UCLB pay [\*\*\*] percent ([\*\*\*]%) of Net Receipts within [\*\*\*] ([\*\*\*]) days after Licensee receives such Net Receipts."

- (k) Clauses 5.8 and 5.10 of the Licence Agreement are hereby deleted in their entirety, without effect on the numbering of the other Clauses within Article 5 of the Licence Agreement.
  - (l) The last paragraph of Clause 5.14 of the Licence Agreement is hereby amended and restated as follows:

"The Licensee shall co-operate with UCLB in good faith to resolve any discrepancies identified during any such inspection and shall pay any undisputed shortfall in the amounts paid to UCLB under this Agreement, together with interest on late payment as specified in Clause 5.12.4, within [\*\*\*] days following receipt of a copy of the independent chartered accountant's report."

(m) Clause 11.2 of the Licence Agreement is hereby amended and restated as follows:

"Each Licence Addendum and the licences granted in this Agreement, shall come into effect on the Commencement Date and, unless terminated earlier in accordance with this Clause 11 or Clause 12.1.2, the licences granted hereunder shall continue in force on a country by country basis until the later of the last payment obligation of Licensee expires under this Agreement. Upon such expiry, Licensee's licenses under this Agreement shall become full-paid, perpetual and irrevocable."

- 3. Warranties. Each Party hereby warrants to the other Party as follows:
- (a) it has the full corporate power and authority to enter into and deliver this Amendment and to perform and consummate the transactions contemplated hereby;
- (b) all corporate acts and other proceedings required to be taken to authorize such execution, delivery, and consummation have been duly and properly taken and obtained;
- (c) this Amendment has been duly executed and delivered by such Party and constitutes a legal, valid, and binding obligation of such Party, enforceable against such Party in accordance with its terms, except as such enforceability may be limited by applicable insolvency and other laws affecting creditor's rights generally or by the availability of equitable remedies; and
- (d) except as expressly amended by this Amendment, the Agreement is in full force and effect in accordance with its terms and, to each Party's knowledge, there exists no breaches, defaults or events which would (with the giving of notice, the passage of time or both) give rise to a breach, default, or other right to terminate or modify the Agreement.

#### 4. Other.

- (a) **Effect of Amendment.** From and after the Amendment Effective Date, all references to the Agreement shall mean the Agreement as amended by this Amendment.
- (b) **Counterparts.** This Amendment may be executed in two or more counterparts, each of which shall be deemed an original but all of which together shall constitute one and the same instrument. Signatures to this Amendment transmitted by fax, by email in "portable document format" (".pdf") or by any other electronic means intended to preserve the original graphic and pictorial appearance of this Amendment shall have the same effect as physical delivery of the paper document bearing original signature.
- (c) **Entire Amendment.** This Amendment contains the entire understanding of the Parties with respect to the subject matter of this Amendment. Except as specifically modified and amended hereby, all of the terms, provisions, requirements and specifications contained in the Agreement remain in full force and effect. Except as otherwise expressly provided herein, the Parties do not intend to, and the execution of this Amendment shall not, in any manner, impair the Agreement, the purpose of this Amendment being simply to amend certain specific provisions of the Agreement only and to confirm and carry forward the Agreement, as hereby amended, in full force and effect. This Amendment may be amended, or any term hereof modified, only by a written instrument executed by both the Parties.
- (d) **Notices.** All notices, requests and other communications hereunder shall be in writing and shall be personally delivered or sent by fax transmission (and promptly confirmed by personal delivery, registered or certified mail or overnight courier) or by registered or certified mail, return receipt requested, postage prepaid, or sent by internationally-recognized overnight courier, in each case to the respective address specified below, or such other address as may be specified in writing to the other party hereto:

# If to MeiraGTx to:

MeiraGTx Limited
92 Britannia Walk,
London N1 7NQ United Kingdom
Fax No.: [•]
Attention: [•]

# If to UCLB to:

UCL Business PLC The Network Building 97 Tottenham Court Road London W1T 4TP United Kingdom Fax No.: +44 (0) 20 76679 9838 Attention: [•]

[Signature Page Follows]

**IN WITNESS WHEREOF**, the Parties have executed this Amendment as of the Amendment Effective Date.

# MEIRAGTX LIMITED

/s/ Richard Giroux By:

Name: Richard Giroux

Chief Operating Officer Title:

# **UCL BUSINESS PLC**

By: /s/ Anne Lane

Name: Anne Lane Title: **Executive Director** 

# **AMENDMENT NO. 3 TO EXCLUSIVE LICENCE AGREEMENT**

This AMENDMENT NO. 3 TO EXCLUSIVE LICENSE AGREEMENT (this "Amendment"), effective as of December 14, 2017 (the "Amendment Effective Date"), is entered into by and between MeiraGTx Limited, having a place of business located at 92 Britannia Walk, London N1 7NQ United Kingdom ("MeiraGTx") and UCL Business PLC, whose registered office is The Network Building, 97 Tottenham Court Road, London W1T 4TP United Kingdom ("UCLB"). MeiraGTx and UCLB are each sometimes referred to herein as a "Party" and collectively referred to herein as the "Parties".

#### WITNESSETH:

WHEREAS, UCLB and Athena Vision Ltd., a company incorporated under the laws of England and Wales under company registration number 09348737 ("Athena") entered into a Licence Agreement dated 4 February 2015, as amended by Amendment No. 1 to Exclusive Licence Agreement, effective as of 27 March 2015 and Amendment No. 2, effective as of July 28, 2017 (as amended, the "Licence Agreement"), pursuant to which UCLB licensed to Athena certain technology and intellectual property relating to ocular gene therapy, which UCLB acquired by assignment from University College London, for development and commercialization by Athena.

**WHEREAS**, pursuant to a Share for Share Exchange Deed made and delivered in 2016 by and among [\*\*\*] (collectively, the "**Transferring Shareholders**"), Athena, and MeiraGTx (the "**Exchange Deed**"), the Transferring Shareholders agreed to sell to MeiraGTx a total of [\*\*\*] in the capital of Athena (the "**Shares**") in exchange for a certain number of shares of MeiraGTx on the terms and conditions of the Exchange Deed.

**WHEREAS,** upon the completion of the sale and purchase of the Shares in accordance with Clause 5 of the Exchange Deed occurring on or about April of 2016 (the "Completion"), MeiraGTx increased its shareholding in Athena from 60% to 100% and Athena became a wholly-owned subsidiary of MeiraGTx.

**WHEREAS,** UCLB, Athena, and MeiraGTx entered into a Deed of Novation and Amendment in 2016 ("**Deed of Novation and Amendment**") pursuant to which the parties thereto agreed to, among other things, novate Athena's rights, obligations, and liabilities under the Licence Agreement to MeiraGTx on the terms and conditions of the Deed of Novation and Amendment (the "**Novation**").

**WHEREAS**, the Novation became effective as of the Completion, the Parties now mutually desire to further amend the Licence Agreement on the terms and conditions set forth in this Amendment.

**NOW THEREFORE**, in consideration of the foregoing statements and the mutual agreements and covenants herein contained, and for other good an valuable consideration, the sufficiency of which are hereby acknowledged, the Parties hereby agree as follows.

- 1. **Definitions**. Except as set forth herein, capitalized terms not otherwise defined or amended in this Amendment shall have the meaning ascribed to them in the Licence Agreement, as amended by this Amendment. References to Articles, Clauses, or Schedules are to the same with all their subparts as they appear in the Licence Agreement. References to Sections are to the numbered paragraphs with all their subparts as they appear in this Amendment.
- 2. **Amendment to the Agreement**. Effective as of the Amendment Effective Date, the Agreement shall be and is hereby amended as set forth in this Section 2:
  - (a) The definition of "Licensed Technology" as defined in Clause 1.1 of the Licence Agreement is hereby amended and restated as follows:
  - "Licensed Technology means Intellectual Property, Patents and Know-how relating to each technology licensed by UCLB to the Licensee under any License Addendum to this Agreement,"
  - 3. Warranties. Each Party hereby warrants to the other Party as follows:
  - (a) it has the full corporate power and authority to enter into and deliver this Amendment and to perform and consummate the transactions contemplated hereby;
  - (b) all corporate acts and other proceedings required to be taken to authorize such execution, delivery, and consummation have been duly and properly taken and obtained;
  - (c) this Amendment has been duly executed and delivered by such Party and constitutes a legal, valid, and binding obligation of such Party, enforceable against such Party in accordance with its terms, except as such enforceability may be limited by applicable insolvency and other laws affecting creditor's rights generally or by the availability of equitable remedies; and
  - (d) except as expressly amended by this Amendment, the Agreement is in full force and effect in accordance with its terms and, to each Party's knowledge, there exists no breaches, defaults or events which would (with the giving of notice, the passage of time or both) give rise to a breach, default, or other right to terminate or modify the Agreement.

#### 4. Other.

- (a) **Effect of Amendment.** From and after the Amendment Effective Date, all references to the Agreement shall mean the Agreement as amended by this Amendment.
- (b) **Counterparts.** This Amendment may be executed in two or more counterparts, each of which shall be deemed an original but all of which together shall constitute one and the same instrument. Signatures to this Amendment transmitted by fax, by email in "portable document format" (".pdf") or by any other electronic means intended to preserve the original graphic and pictorial appearance of this Amendment shall have the same effect as physical delivery of the paper document bearing original signature.

- (c) Entire Amendment. This Amendment contains the entire understanding of the Parties with respect to the subject matter of this Amendment. Except as specifically modified and amended hereby, all of the terms, provisions, requirements and specifications contained in the Agreement remain in full force and effect. Except as otherwise expressly provided herein, the Parties do not intend to, and the execution of this Amendment shall not, in any manner, impair the Agreement, the purpose of this Amendment being simply to amend certain specific provisions of the Agreement only and to confirm and carry forward the Agreement, as hereby amended, in full force and effect. This Amendment may be amended, or any term hereof modified, only by a written instrument executed by both the Parties.
- (d) Notices. All notices, requests and other communications hereunder shall be in writing and shall be personally delivered or sent by fax transmission (and promptly confirmed by personal delivery, registered or certified mail or overnight courier) or by registered or certified mail, return receipt requested, postage prepaid, or sent by internationally-recognized overnight courier, in each case to the respective address specified below, or such other address as may be specified in writing to the other party hereto:

#### If to MeiraGTx to:

MeiraGTx Limited 92 Britannia Walk. London N1 7NQ United Kingdom Fax No.: [•] Attention: [•]

## If to UCLB to:

UCL Business PLC The Network Building 97 Tottenham Court Road London W1T 4TP United Kingdom Fax No.: +44 (0) 20 76679 9838

Attention: [•]

[Signature Page Follows]

**IN WITNESS WHEREOF**, the Parties have executed this Amendment as of the Amendment Effective Date.

# MEIRAGTX LIMITED

By: /s/ Richard Giroux
Name: Richard Giroux

Title: Chief Operating Officer

**UCL BUSINESS PLC** 

By: /s/ Anne Lane

Name: Anne Lane
Title: Executive Director

# LICENCE AGREEMENT

between

**UCL Business Plc** 

and

# MeiraGTx UK II Limited

Dated: 28th July 2017

Ref:

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## THIS AGREEMENT is made

July 28, 2017

## **BETWEEN:**

(1) **UCL BUSINESS PLC**, a company incorporated in England and Wales under company registration number 02776963 whose registered office is The Network Building, 97 Tottenham Court Road, London W1T 4TP ("UCLB");

an

(2) **MEIRAGTX UK II LIMITED, (FORMERLY KADMON GENE THERAPY HOLDINGS LIMITED)**, a company incorporated in England and Wales with registered number 09348737 and having its registered office at 92 Britannia Walk, London, United Kingdom, N1 7NQ (the "Licensee").

#### WHEREAS:

- A. University College London ("UCL"), the Medical Research Council ("MRC"), Massachusetts Eye and Ear Infirmary ("MEEI"), and National Institutes of Health which is a part of the U.S. Department of Health and Human Services ("NIH") developed certain technology and owned certain intellectual property rights relating to a gene therapy for treating retinitis pigmentosa using an abbreviated form of a human Retinitis Pigmentosa GTPase Regulator (RPGR) gene.
- B. The MRC has entered into an assignment agreement with UCLB in which it assigned all of its right, title and interest in and to the Patent Rights as defined in that assignment to UCLB.
- C. UCL and [\*\*\*], an employee of UCL, have entered into an assignment agreement with UCLB in which UCL and [\*\*\*] assigned all of their right, title and interest in and to the Assigned Property as defined in that assignment to UCLB.
- D. The NIH has licensed, maintaining certain reserved rights, all of its right, title and interest in and to the Patents, the Know-how and the Materials to MEEI. MEEI has granted to UCLB, maintaining certain reserved rights, an exclusive licence under the Patents and to use the Know-how and Materials.
- E. The Licensee wishes to acquire rights under the Patents and to use the Know-how and the Materials for the development and commercialisation of Licensed Products in the Field and in the Territory, all in accordance with the provisions of this Agreement.
- F. MeiraGTx UK II Ltd. aims to develop and commercialize the Licensed Product in the Field and in the Territory.
- G. It is the policy of UCLB that its activities in licensing intellectual property take into consideration ethical and socially responsible licensing principles, including ensuring that Licensed Products are made available to fulfil unmet needs in Developing Countries, and the Licensee acknowledges and agrees to carry out its activities under this Agreement in a manner which complies with ethical and socially responsible licensing principles and which is designed to fulfil such needs, all in accordance with the provisions of this Agreement.

## NOW IT IS AGREED as follows:

# 1. DEFINITIONS

**1.1** In this Agreement:

**Agreement** means this agreement (including the Schedules);

Affiliate in relation to a Party, means any entity or person that Controls, is Controlled by, or is under common Control with that Party;

**At-Cost Markets** means those markets in Developing Countries [\*\*\*];

Claims means all demands, claims and liability (whether criminal or civil, in contract, tort or otherwise) for losses, damages, costs and expenses of any nature whatsoever and all costs and expenses (including legal costs) incurred in connection therewith;

**Commencement Date** means the date of last signature of this Agreement;

Commercial Third Party means a commercial entity that is not a Party of this Agreement;

**Competing Product** means any product, whether ready for marketing or in development that competes, or is likely to compete once developed, with any Licensed Product;

Confidential Information means the Know-how, the Materials and all other technical or commercial information that:

- a) in respect of information provided in documentary form or by way of a model or in other tangible form, at the time of provision is marked or otherwise designated to show expressly that it is imparted in confidence or which a reasonable person would expect to be confidential; and
- b) in respect of information that is imparted orally, any information that the Disclosing Party or its representatives informed the Receiving Party at the time of disclosure or which a reasonable person would expect to be confidential;

**Control** means direct or indirect beneficial ownership of 50% (or, outside a Party's home territory, such lesser percentage as is the maximum permitted level of foreign investment) or more of the share capital, stock or other participating interest carrying the right to vote or to distribution of profits of that Party, as the case may be:

**Cost-Based Price** means, in respect of each Licensed Product, [\*\*\*];

**Developing Country** or **Developing Countries** refers to those countries that are:

- a) [\*\*\*]; and
- b) to the extent not included in a);
  - i) defined as of the Commencement Date [\*\*\*]; and
  - ii) all other countries that may be mutually agreed to by UCL and Licensee from time to time;

**Developing Country Manufacturer** means a manufacturer of pharmaceutical products that is able to efficiently manufacture (either within or outside the Developing Country in which the At-Cost market exists), distribute and supply the Licensed Product in an At-Cost market at a Cost-Based Price;

**Diligent Efforts** means exerting such efforts and employing such resources as would normally be exerted or employed by [\*\*\*], when utilizing sound and reasonable scientific, medical and business practice and judgment in order to develop the product in a timely manner and generate an economic return to the Parties from its commercialisation;

**Disclosing Party** has the meaning given in Clause 3.3;

Field means ocular gene therapy;

**First Commercial Sale** means the first sale to a third party of a Licensed Product in a given regulatory jurisdiction after all regulatory and marketing approvals have been obtained for such Licensed Product in such jurisdiction. A sale shall not be deemed to have occurred if a Licensed Product is provided pursuant to an early access or compassionate use

**Indemnitees** has the meaning given in Clause 10.6;

**Intellectual Property** means any and all patents, utility models, registered designs, unregistered design rights, copyright, database rights, rights in respect of confidential information, rights under data exclusivity laws, rights under orphan drug laws, rights under unfair competition laws, property rights in biological or chemical materials, extension of the terms of any such rights (including supplementary protection certificates), applications for and the right to apply any of the foregoing registered property and rights, and similar or analogous rights in any part of the Territory;

### Know-how means:

- a) the inventions claimed in the Patents; and
- b) the technical information relating to the inventions claimed in the Patents and data described in the Part B of Schedule 1

**Licensed Products** means any and all products that are developed, manufactured, used, or sold by or on behalf of the Licensee or its Affiliates or Sub-licensees and which (a) are within (or are manufactured using a process described in) the Patents; and/or (b) incorporate, or their development or manufacture makes use of, any of the Know-how and/or the Materials.

Materials means any and all of the materials referred to in Part C of Schedule 1.

**MEEI Indemnitees** has the meaning given in Clause 10.7.1.

Net Sales Value means in respect of the Licensed Products after their First Commercial Sale:

- a) the gross invoiced price of Licensed Products sold by the Licensee or its Affiliates or Sub-licensees in arm's length sales of Licensed Products for cash consideration; and/ or
- b) where the sale is not at arm's length and/ or is for or includes a non-cash consideration, or if Licensed Products used or subject to Clause 6.9, disposed of for free by the Licensee or its Affiliates the relevant open market price for the Licensed Product in the country or territory in which the sale, use or disposal takes place or if the relevant open market price is not ascertainable, a reasonable price, assessed on an arm's length basis therefor,

# after deduction of all documented:

- normal trade discounts (but excluding early payment discounts) actually granted and any credits actually given for rejected or returned Licensed Products;
- ii) costs of packaging, insurance, carriage and freight, provided in each case that the amounts are separately charged to the purchaser on the relevant invoice;
- iii) deductions for actual bad debt in connection with sales of Licensed Product (provided that Licensee will use Diligent Efforts to obtain payment of such bad debt);
- iv) value added tax or other sales tax; and
- v) import duties or similar applicable government levies charged to the purchaser on the relevant invoice.

provided that such deductions do not exceed reasonable and customary amounts in the markets in which such sales occurred. Sales of Licensed Products between the Licensee and its Affiliates shall not be taken into account for the purposes of calculating "Net Sales Value" unless there is no subsequent sale to a third party in an arm's length transaction for a cash consideration;

Parties means UCLB and the Licensee, and "Party" shall mean either of them;

**Patents** means any and all of the patents and patent applications referred to in Part A of Schedule 1, including any continuations, continuations in part, extensions, reissues, divisions, and any patents, supplementary protection certificates and similar rights that are based on or derive priority from the foregoing.

# **Principal Investigators** means [\*\*\*].

**Reasonable Developing Country Licence Terms** means terms that meet the requirements of both UCL's ethical and socially responsible licensing policy, which is at: (http://www.ucl.ac.uk/enterprise/about/policies/files/Global\_access-final.pdf) and the following principles:

- a) the Licensee shall [\*\*\*];
- b) the Developing Country licence terms [\*\*\*] that shall not [\*\*\*];
- c) if the Developing Country Manufacturer is granted any exclusive rights, the continued grant of those rights shall be conditional upon the Developing Country Manufacturer supplying At-Cost Markets at a Cost-Based Price and meeting market demand in that market; and
- d) the Licensee may impose reasonable conditions, including as to use of trade marks, trade dress, format and pack size, to differentiate the Licensed Product when sold in the At-Cost market from Licensed Products sold in other markets and to prohibit their export into other markets and territories, provided that such conditions or their implementation do not act as an unreasonable barrier to the prompt and efficient supply of Licensed Product in the At-Cost market;

**Receiving Party** means has the meaning given in Clause 3.3;

**Regulatory Exclusivity** means, with respect to a Licensed Product, any exclusive rights or protection which are recognised, afforded or granted by any Regulatory Authority in any country or region with respect to the Licensed Product other than through patent rights;

**Sub-licensee** means any third party (other than an Affiliate) to whom the Licensee grants a sub-licence of its rights under this Agreement in accordance with Clause 2.3;

Territory means Worldwide;

**Valid Claim** means a claim of a patent or patent application that has not been abandoned or allowed to lapse or expired or been held invalid or unenforceable by a court of competent jurisdiction in a final and non-appealable judgment.

### 2. GRANT OF RIGHTS

#### 2.1 Licence

UCLB hereby grants to the Licensee and its Affiliates, and the Licensee hereby accepts on its own behalf and on behalf of its Affiliates, subject to the provisions of this Agreement:

2.1.1 an exclusive (even as to UCL) licence under the Patents, with the right to sub-license, subject to Clause 2.3, to develop, commercialise, manufacture, have manufactured, use, sell and have sold Licensed Products only in the Field and in the Territory; and

- 2.1.2 an exclusive (even as to UCL) licence to use the Know-how and the Materials, with the right to sub-license, subject to Clause 2.3, to develop, commercialise, manufacture, have manufactured, use, sell and have sold Licensed Products only in the Field and in the Territory.
- 2.2 UCLB shall at the Licensee's request and cost execute such formal licences as may be necessary to enable the Licensee to register the licences granted to it under this Agreement with the Patent Offices in the relevant Territory. Such formal licence will reflect the terms of this Agreement where possible and for the avoidance of doubt if there is a conflict in the terms of such formal licence and this Agreement, the terms of this Agreement shall prevail. The Licensee shall ensure that this Agreement shall not form part of any public record, except where disclosure of the terms of this Agreement are required by applicable law, rule or regulation (including the rules or regulations of a stock exchange upon which the Licensee's shares are sold).

# 2.3 Sub-Licensing

The Licensee shall have the right to grant sub-licences under the licence in Clause 2.1 to its Affiliates or other third parties through one or more levels of Sub-licensees except that the Licensee may not grant such a sub-licence to any person or the Affiliates of any person involved in: the tobacco industry (as defined by the Cancer Research UK Code of Practice on Tobacco Industry Funding to Universities detailed in Schedule 3); arms dealing; gambling operations; the promotion of violence; child labour or any other illegal activity. A grant of any sub-licence shall be conditional on the following:

- (a) The Licensee shall enter into a written agreement with each Sub-licensee and shall ensure that the provisions of each sub-licence are consistent with the provisions of this Agreement, and the Licensee shall ensure that:
  - (i) the sub-licence sets out all the proposed terms agreed between the Licensee and the Sub-licensee, including, in particular, all terms as to remuneration:
  - (ii) the Sub-licensee will maintain complete and accurate records in sufficient detail to permit UCLB to confirm the accuracy of the calculation of royalty payments under this Agreement; and
  - (iii) the sub-licence imposes obligations of confidentiality on the Sub-licensee which are no less onerous than those set out in Clause 3.3.
- (b) The Licensee shall procure that each Sub-licensee complies fully at all times with the provisions of its sub-licence.

- (c) The Licensee shall be liable for all acts and omissions of its Sub-licensees that, if committed by the Licensee, would constitute a breach of any of the provisions of this Agreement.
- (d) The Licensee shall provide UCLB with a copy of any sub-licence [\*\*\*] ([\*\*\*]) days after execution of such sub-licence, provided that the Licensee may redact confidential or proprietary terms from such copy, including financial terms.
- (e) Each sub-licence shall terminate automatically upon termination of this Agreement for any reason (but not expiry of this Agreement under Clause 12.1) except where:
  - (i) the Sub-licensee was not implicated in or at fault in any circumstances which led to the termination of this Agreement;
  - (ii) the benefit (but not the burden) of the sub-licence agreement is validly assigned to UCLB in writing within [\*\*\*] ([\*\*\*]) days following the date of termination of this Agreement; and
  - (iii) following assignment, the Sub-licensee observes in full the terms of the sub-licence agreement including paying all sums due to the Licensee under the sub-licence agreement directly to UCLB in a timely manner, in which case the Sub-licensee's rights to use the Patents, the Know-How and/or the Materials shall continue in full force and effect in accordance with the terms of the relevant sub-licence agreement.

# 2.4 Reservation of Rights

UCLB reserves for itself and UCL the non-exclusive, irrevocable, worldwide, royalty-free right to:

- (a) Use the Patents, the Know-how and the Materials in the Field solely for academic research, publication and teaching; and
- (b) Grant licences to academic third parties to use the Patents, the Know-how and the Materials solely in academic research collaborations with UCL; and
- (c) Grant licences of the Patents, the Know-how and the Materials to post graduate students of UCL solely for the purpose of conducting a programme of post graduate academic research.

In exercising the rights described in Clause 2.4.1 (b) and (c), UCL and UCLB shall comply with the provisions of Clause 3 as regards confidentiality of the Know-how.

- 2.4.2 UCLB reserves for MEEI the non-exclusive, irrevocable, worldwide, royalty-free right to:
  - (a) use the Patents, the Know-how and the Materials solely for MEEI's own internal non-commercially funded research, publication and teaching, excluding use in human subjects, clinical trials or for diagnostic purposes involving human subjects;
  - (b) to license other academic institutions to use the Patents, the Know-how and the Materials solely in non-commercially funded academic research collaborations with MEEI, excluding research for use in human subjects, clinical trials or research for diagnostic purposes involving human subjects; and
  - (c) to grant licences of the Patents, the Know-how and the Materials to other academic, governmental or not-for-profit organisations to use the Patents, the Know-how and the Materials solely for non-commercial research purposes and not for use in human subjects, clinical trials or for diagnostic purposes involving human subjects.
- 2.4.3 MEEI and UCLB will refer a request from a third party for a licence to use the Patents in clinical trials or for diagnostic purposes involving human subjects to the Licensee, and the Licensee shall liaise directly with such third party.
- 2.4.4 UCLB reserves for the U.S. Government only the irrevocable, royalty-free, paid-up right to practice and have practiced the rights under the Patents throughout the world by or on behalf of the U.S. Government and on behalf of any foreign government or international organisation pursuant to any existing or future treaty or agreement to which the U.S. Government is a signatory.
- 2.4.5 UCLB reserves the right, if required by the NIH, to grant sub-licenses of the rights under the Patents to responsible applicants, on terms that are reasonable under the circumstances when necessary to fulfill health or safety needs or when necessary to meet requirements for public use specified by U.S. Federal regulations.
- 2.4.6 UCLB reserves for the NIH only the right to require the Licensee, to grant sub-licenses of the rights under the Patents to responsible applicants, on terms that are reasonable under the circumstances when necessary to fulfill health or safety needs or when necessary to meet requirements for public use specified by U.S. Federal regulations.
- 2.4.7 In addition to the reserved rights of Clause 2.4.5, UCLB reserves the right, should it be required by the NIH, to grant a non-transferable, non-exclusive license to make and to use any tangible embodiment of the Patents and to practice any process(es)

- included within the Patents for purposes of internal research and not for purposes of commercial manufacture or distribution or in lieu of purchase, on reasonable terms and conditions.
- 2.4.8 In addition to the reserved rights of Clause 2.4.6, UCLB reserves for the NIH only the right to require the Licensee to grant a non-transferable, non-exclusive license to make and to use any tangible embodiment of the Patents and to practice any process(es) included within the Patents for purposes of internal research and not for purposes of commercial manufacture or distribution or in lieu of purchase, on reasonable terms and conditions.
- 2.4.9 UCLB reserves for the MRC the non-exclusive right to:
  - (a) use the Patents for its own internal, not-for-profit and non-commercially funded research, teaching and publicity, excluding use in human subjects, clinical trials or for diagnostic purposes involving human subjects; and
  - (b) licence academic institutions who employ Professor Alan Wright and Dr Xinhua Shu to use the Patents in not-for-profit and non-commercially funded research, excluding research for use in human subjects, clinical trials or research for diagnostic purposes involving human subjects.
- 2.4.10 Except for the licences expressly granted by this Clause 2, UCLB grants no rights to the Licensee under this Agreement to or under any intellectual property other than the Patents, the Know-how and the Materials and hereby reserves all rights under the Patents, the Know-how and the Materials outside the Field.
- 2.4.11 Nothing in this Agreement shall limit or otherwise affect UCL's ability to apply for non-commercial grant funding or comply with such grant terms and conditions. In the event that any terms of this Agreement conflicts with the terms of any non-commercial grant funding, the Parties shall negotiate in good faith to amend the terms of this Agreement to allow UCL to access such funding provided that nothing herein shall require the Licensee to agree to alter or modify the scope of the licence granted to it in this Clause 2.

### 2.5 Affiliates

The Licensee shall:

- 2.5.1 ensure that its Affiliates comply fully with the terms of this Agreement;
- 2.5.2 be responsible for any breach of or non-compliance with this Agreement by its Affiliates as if the breach or non-compliance had been a breach or non-compliance by the Licensee;

- 2.5.3 indemnify in accordance with Clause 10.6 each of the Indemnitees against any Claims which are awarded against or suffered by any of the Indemnitees as a result of any breach of or non-compliance with this Agreement by its Affiliates; and
- 2.5.4 ensure that if any Affiliate ceases to be an Affiliate as a result of a change of Control or otherwise, that unless a sub-licence agreement in accordance with Clause 2.3 is entered into with such an Affiliate, such former Affiliate immediately upon such cessation:
  - (a) ceases developing, manufacturing, having manufactured, using, selling and/ or having sold Licensed Products and ceases all use or exploitation of the Licensed Technologies, for as long as any of the relevant Patents remains in force and/or the Know-how remains confidential;
  - (b) returns to the Licensee or destroys any documents or other materials in the former Affiliate's possession or under its control and that contain Confidential Information provided under this Agreement relating to the Licensed Technologies and/ or Licensed Products;
  - (c) to the extent possible, takes all action necessary to have any product licences, marketing authorisations, pricing and/ or reimbursement approvals (and any applications for any of the foregoing) which relate to Licensed Products transferred into the name of the Licensee.

# 3. KNOW-HOW AND CONFIDENTIAL INFORMATION

# 3.1 Provision of Know-how

Within [\*\*\*] ([\*\*\*]) days following the Commencement Date, UCLB shall deliver to the Licensee the Materials and a copy of the Know-how.

# 3.2 Confidentiality of Know-how and Materials

The Licensee undertakes that for so long as the Know-how and / or the Materials remains confidential, it shall (and shall ensure that its Affiliates and Sub-licensees) take all reasonable precautions to prevent unauthorised access to the Know-how and the Materials and protect the Know-how and the Materials in the same manner as it (or they) protect(s) its (or their) own proprietary information, and shall not (and shall ensure that its Affiliates and Sub-licensees do not) use the Know-how or the Materials for any purpose, except as expressly licensed hereby and in accordance with the provisions of this Agreement. For the avoidance of doubt, to the extent that any Materials, Know-how or information relating to the Patents falls within the public domain (without any breach of this Agreement or any other obligation of confidentiality), then UCL, the Founders and UCLB shall be free to use such information without restriction in the same way that any third party would have the freedom to use it.

# 3.3 Confidentiality Obligations

Each Party ("Receiving Party") undertakes:

- 3.3.1 to maintain as secret and confidential all Confidential Information obtained from the other Party ("Disclosing Party") in the course of or in anticipation of this Agreement and to respect the Disclosing Party's rights therein;
- 3.3.2 to use such Confidential Information only for the purposes of or as permitted by this Agreement; and
- 3.3.3 subject to Clause 3.4, to disclose such Confidential Information only to those of its employees, contractors, Affiliates, and Sub-licensees (if any) to whom and to the extent that such disclosure is reasonably necessary for the purposes of this Agreement.

### 3.4 Permitted Disclosure

- 3.4.1 UCLB shall have the right to provide the MRC and MEEI with brief annual updates on the status of the commercial exploitation of the Patents, the Materials and the Know-how.
- 3.4.2 UCLB shall have the right to disclose to the MRC under binding obligations of confidentiality:
  - (a) that it has entered into this Agreement with the Licensee;
  - (b) details of all milestone payments and royalty payments provided for in this Agreement;
  - (c) a copy of the Initial Development Plan;
  - (d) details of any development milestones provided for in this Agreement
- 3.4.3 the Licensee shall have the right to disclose Confidential Information received from UCLB to:
  - (a) potential or actual customers of Licensed Products to the extent reasonably necessary to promote the sale or use of Licensed Products and provided that the customer has agreed to confidentiality provisions at least as restrictive as set forth herein;
  - (b) to existing or potential Sub-licensees, collaborators, investors or lenders provided that such third parties have agreed to confidentiality provisions at least as restrictive as set forth herein; and
  - (c) to its Board of Directors (or similar governing body) and its counsel, accountants and other professional advisers.

# 3.5 Exceptions to Obligations

The provisions of Clause 3.3 shall not apply to Confidential Information which the Receiving Party can demonstrate by reasonable written evidence:

- 3.5.1 was, prior to the Commencement Date, in the possession of the Receiving Party and at its free disposal and was not obtained or otherwise acquired directly or indirectly from the Disclosing Party or its Affiliates or their respective employees, students or representatives; or
- 3.5.2 is subsequently disclosed to the Receiving Party without any obligations of confidence by a third party; or
- 3.5.3 is or becomes generally available to the public through no act or default of the Receiving Party or its agents, employees, Affiliates or Sub-licensees; or
- 3.5.4 the Receiving Party is required to disclose by or to the courts of any competent jurisdiction, or to any government regulatory agency or financial authority, provided that the Receiving Party shall:
  - (a) inform the Disclosing Party as soon as is reasonably practicable;
  - (b) at the Disclosing Party's request and cost seek to persuade the court, agency or authority to have the information treated in a confidential manner, where this is possible under the court, agency or authority's procedures; and
  - (c) where the disclosure is unavoidable, limit the disclosure of Confidential information to the minimum extent required by law; or
- 3.5.5 which a Party is advised by its information officer that it is required to disclose under the Freedom of Information Act 2000 or the Environmental Information Regulations 2004.

### 3.6 Disclosure to Employees

The Receiving Party shall procure that all of its employees, contractors, Affiliates and Sub-licensees who have access to any of the Disclosing Party's Confidential Information to which Clause 3.3 applies, shall be made aware of the obligations of confidence and enter into written undertakings of confidentiality at least as restrictive as those set forth herein (which it undertakes to enforce and for which it is legally responsible) and the Receiving Party shall only disclose the Disclosing Party's Confidential Information to those of its subsidiaries, employees, and officers as need to have access thereto wholly necessarily and exclusively for the purposes of this Agreement.

# 4. RESPONSE TO NIH

If the Licensee is notified of a determination of a conflict of interest regarding the Patents by the NIH it shall provide a response to such determination to the NIH within the period given by NIH to respond to such determination.

# 5. CONSIDERATION

# 5.1 Initial Payment

On or before the Commencement Date, the Licensee shall pay to UCLB a non-refundable, non-deductible payment of \$17,888.00 (seventeen thousand eight hundred and eighty eight dollars) which UCLB will then pay to MEEI in order to reimburse all of the costs and expenses incurred by MEEI in respect of drafting, applying for and prosecuting the Patents prior to 18 May 2016.

# 5.2 Milestone Payments

Within [\*\*\*] ([\*\*\*]) days following achievement of each of the following milestone events by Licensee, its Affiliates or Sub-licensees, the Licensee shall notify UCLB in writing that the relevant milestone event has been achieved, provide documentary evidence of such achievement as appropriate and pay to UCLB, within a period of [\*\*\*] days, the amount(s) set out next to such milestone event below:

Milestone Event		Amount to be paid		
[**	*]	£	[***]	
[**	*]	£	[***]	

# 5.3 Annual Management Fees

On each date referred to in the following table, the Licensee shall pay to UCLB the annual management fee set out next to such date in the table.

Date	Amount t	to be paid
Upon each anniversary of the Commencement Date until [***]	£	50,000

# 5.4 Sales Linked Milestone Payments

Upon achievement of each of the sales linked milestones set out in the following table by the Licensee, its Affiliates or Sub-licensees, the Licensee shall notify UCLB in writing that the relevant sales linked milestone has been achieved, provide the relevant documentary evidence and pay to UCLB the amount(s) set out next to such event in the table:

Sales Linked Milestones	Amount to be paid	
When Net Sales Value reaches £[***]	£	[***]
On the next $\mathfrak{L}[***]$ of Net Sales Value (when sales cumulatively reach $\mathfrak{L}[***]$ )	£	[***]
On the next £[***] of Net Sales Value (When sales cumulatively reach		
£[***])	£	[***]
On the next £[***] of Net Sales Value (when sales cumulatively reach		
$\mathfrak{E}[***]$	£	[***]
On the next £[***] of Net Sales Value (when sales cumulatively reach		
$\mathfrak{E}[***]$	£	[***]
On the next £[***] of Net Sales Value (when sales cumulatively reach		
£[***])	£	[***]

# 5.5 Royalties on Net Sales

For each Licensed Product in each country, the Licensee shall pay to UCLB a royalty of [\*\*\*]% ([\*\*\*] per cent) being a percentage of the Net Sales Value of all Licensed Products sold by Licensee, its Affiliates or Sub-licensees. The Licensee's obligations to pay such royalty for a given Licensed Product in a given country shall begin after the First Commercial Sale of such Licensed Product in such country and shall end on the later to occur of the following: (a) expiration of the last Valid Claim of a Patent claiming such Licensed Product in such country; or (b) the tenth (10th) anniversary of the date of such First Commercial Sale in such country; or (c) the expiration of any Regulatory Exclusivity with respect to all Licensed Products in the relevant country.

# 5.6 Intentionally omitted

### 5.7 Combination Products

If any Licensed Products are incorporated in any other product ("Combination Product") sold by the Licensee or its Affiliates and the Licensed Product is not priced separately from the Combination Product, the Net Sales Value of such Licensed Product shall be deemed to be the fair market value of the Licensed Product in the country of sale when sold separately or if not sold separately in the country of sale, in comparable countries and territories or if neither of the foregoing apply, a reasonable amount which fairly reflects the value of the Licensed Product within the Combination Product assuming the Licensed Product is not being sold as a loss leader.

#### 5.8 Payment Frequency

Royalties due under this Agreement, except for the payments due under Clauses 5.1, 5.2, 5.3 and 5.4, which are payable upon the date/time specified in Clauses 5.1, 5.2, 5.3, and 5.4 as appropriate, shall be paid within [\*\*\*] ([\*\*\*]) days following the end of each calendar quarter ending on 31 March, 30 June, 30 September and 31 December in each year, in respect of sales of Licensed Products made during such quarter, and within [\*\*\*] ([\*\*\*]) days following the termination of this Agreement.

### 5.9 Payment terms

All sums due under this Agreement:

- 5.9.1 are exclusive of Value Added Tax which where applicable will be paid by the Licensee to UCLB in addition;
- 5.9.2 shall be paid in pounds sterling in cash by transferring an amount in aggregate to the following Account name: UCL Business Plc, Sort Code: 20 10 53, Account number: 30782270, Address: Barclays Bank Plc, PO Box 11345, London, W12 8GG, and in the case of income or amounts received by the Licensee or its Affiliates in a currency other than pounds sterling, the royalty shall be calculated in the other currency and then converted into equivalent pounds sterling at the relevant daily spot rate for that currency as quoted in the Financial Times newspaper on the last business day of the quarter in relation to which the royalties are payable;
- 5.9.3 will be made without any set-off, deduction or withholding except as may be required by law. If the Licensee is required by law to make any deduction or to withhold any part of any amount due to UCLB under this Agreement, the Licensee will give to UCLB proper evidence of the amount deducted or withheld and payment of that amount to the relevant taxation authority, and will do all things in its power to enable or assist UCLB to claim exemption from or, if that is not possible, to obtain a credit for the amount deducted or withheld under any applicable double taxation or similar agreement from time to time in force; and
- 5.9.4 shall be made by the due date, failing which UCLB may charge interest on any outstanding amount on a daily basis at a rate equivalent to [\*\*\*]% above the Bank of England pound sterling base rate then in force in London.

# 5.10 Royalty Statements

The Licensee shall send to UCLB, at the same time as each royalty payment is made in accordance with Clause 5.5, a statement setting out for the relevant calendar quarter:

- 5.10.1 in respect of each territory or region in which Licensed Products are sold;
- 5.10.2 the types of Licensed Product sold;
- 5.10.3 the quantity of each type sold;
- 5.10.4 the total invoiced price for each type of Licensed Product sold;
- 5.10.5 where relevant, details of any Licensed Products that have been sold other than on arm's length terms for a cash consideration, including the relevant open market price or (if not available) the reasonable price attributed thereto;
- 5.10.6 the amounts deducted from the Net Sales Value as referred to in paragraph (i) to (iv) of that definition (broken down on a product by product and category by category basis); and
- 5.10.7 the aggregate royalties on Net Sales Value due to UCLB;

in each case expressed both in local currency and pounds sterling and showing the conversion rates used, during the period to which the royalty payment relates.

### 5.11 Records

The Licensee shall keep at its normal place of business detailed and up to date records and accounts showing the quantity, description and invoiced price or non-cash consideration for all Licensed Products sold by it or its Affiliates or on its or its Affiliates' behalf, broken down in each case on a country by country basis, and being sufficient to ascertain the payments due to UCLB under this Agreement.

The Licensee shall make such records and accounts available, on reasonable notice, for inspection during business hours by an independent chartered accountant nominated by UCLB for the purpose of verifying the accuracy of any statement or report given by the Licensee to UCLB under this Clause 5.11. The Licensee shall co-operate reasonably with any such accountant, and shall promptly provide all information and assistance reasonably requested by such accountant. The accountant shall be required to keep confidential all information learnt during any such inspection, and to disclose to UCLB only such details as may be necessary to report on the accuracy of the Licensee's statement or report. UCLB shall be responsible for the accountant's charges unless the accountant certifies that there is an inaccuracy of more than [\*\*\*]% ([\*\*\*] percent) in any royalty statement, in which case the Licensee shall pay his charges in respect of that inspection.

The Licensee shall ensure that UCLB has the same rights as those set out in this Clause 5.11 in respect of the Licensee's Affiliates and Sub-licensees.

The Licensee shall co-operate with UCLB in good faith to resolve any discrepancies identified during any such inspection and shall pay any shortfall in the amounts paid to UCLB under this Agreement, together with interest on late payment as specified in Clause 5.9.4, within 30 days following receipt of a copy of the independent chartered accountant's report.

### 5.12 Accounting Standards

Where this Agreement requires a financial calculation to be made or an action to be taken, such calculation or action will be made or taken in accordance with the generally accepted accounting principles from time to time approved by the United Kingdom's Financial Reporting Council, or any successor body, applicable as at the date on which such calculation or action is made or taken.

# 6. COMMERCIALISATION

# 6.1 General Diligence

The Licensee shall use Diligent Efforts to develop and commercially exploit Licensed Products throughout the Territory (including obtaining all and any regulatory approvals which may be required to market and sell the Licensed Products) and to maximise sales for the benefit of both Parties.

# 6.2 Competing Activities

The Licensee shall notify UCLB in confidence if it or any of its Affiliates or its Sub-licensees commences any marketing, sale or commercialisation of any Competing Product or enters into an agreement with any other person with respect to any such activities.

# 6.3 Development Plan

The Licensee's initial plan for developing and commercialising Licensed Products is set out in Schedule 5 (the "Initial Development Plan"). The Licensee shall provide to UCLB on each anniversary of the Commencement Date a written update to the Initial Development Plan that shall:

- 6.3.1 report on all activities conducted under this Agreement by the Licensee and its Affiliates and Sub-licensees since the Commencement Date or the date of the previous update (as appropriate);
- 6.3.2 (where applicable) set out the milestone events achieved since the Commencement Date or the date of the previous update (as appropriate) and the Licensee's reasonable estimate of the dates for achieving any future milestone events;

- 6.3.3 set out the current and projected activities being taken or planned to be taken by the Licensee and its Affiliates and Sub-licensees to bring Licensed Products to market, and to maximise the sale of Licensed Products in the Territory; and
- 6.3.4 set out the Licensee's projected sales of Licensed Products (based on the Licensee's current forecasts) for each of the next [\*\*\*] ([\*\*\*]) years following the date of the report.

UCLB's receipt or approval of any update to the Updated Development Plan shall not be taken to waive or qualify the Licensee's obligations under Clause 6.1.

### 6.4 Annual Meeting

In respect of the Licensed Technology, the Licensee will on UCLB's request meet with UCLB at least once per calendar year, following the submission of the update to the relevant Development Plan pursuant to Clause 6.3, to discuss progress with development and commercialisation of the Licensed Technology and where relevant the Licensee's efforts to maximise sales of Licensed Products.

# 6.5 Reporting of First Commercial Sale

The Licensee will, for each Licensed Technology, promptly notify UCLB in writing of the First Commercial Sale of each Licensed Product on a commercial basis in each country within the Territory.

### 6.6 Reporting for Impact Purposes

- 6.6.1 The Licensee acknowledges that part of UCLB's purpose in licensing the Patents, Know-how and Materials to the Licensee pursuant this Agreement is to ensure that the Patents, Know-how and Materials are made available for use and commercial exploitation with the intention of benefitting society and the economy. In order to enable UCLB and UCL to monitor the benefit that they are providing, and to enable UCL to demonstrate the impact of its research activities, to society and the economy, the Licensee will upon request provide to UCLB [\*\*\*], a written report describing in reasonable detail how it has used the Patents, Know-how and Materials, and the societal and economic benefits generated therefrom.
- 6.6.2 UCLB shall notify and seek permission from the Licensee in advance, in writing if it wishes to use any written reports received from the Licensee (and the information contained therein) pursuant to Clause 6.6.1 in applications for research or other grant related funding and in submissions to Higher Education funding bodies such as HEFCE and/ or HEIF (or any replacements for either of those entities) and like entities, supplying a written copy of the application for research or other grant related funding or submission (or the relevant sections thereof). The Licensee will

respond to UCLB in writing within [\*\*\*] ([\*\*\*]) days of receipt of such written information and subject to the removal of any confidential information as notified in such written request by the Licensee, UCLB and UCL shall be entitled to submit the approved applications for research or other grant related funding and in submissions to Higher Education funding bodies such as HEFCE and/ or HEIF (or any replacements for either of those entities) and like entities.

### 6.7 Quality

The Licensee shall ensure that all of the Licensed Products marketed by it and its Affiliates and Sub-licensees are of satisfactory quality and comply with all applicable laws and regulations in each part of the Territory.

### 6.8 Marking of Licensed Products

To the extent permitted under the laws of any country, the Licensee shall mark and cause its Affiliates and Sub-Licensees to mark each Licensed Product with the number of each issued Patent which applies to the Licensed Product and a statement that such Licensed Products are sold under licence from UCL Business plc.

### 6.9 Disposals of Licensed Products for Free

Notwithstanding the terms of Clause 6.1, the Licensee shall be entitled to supply a reasonable number of Licensed Products to third parties free of charge as promotional items for the purpose of establishing a market for the Licensed Products in the relevant country or territory or for research, evaluation and testing purposes, or for clinical development, provided that the quantity of Licensed Products supplied for free (or for the cost of manufacture) in each country or territory is not excessive and is in line with normal industry practice in such country or territory. Any Licensed Products disposed of to third parties in accordance with this Clause 6.9 shall not be taken into account for the purposes of calculating Net Sales Value.

### 6.10 Referral to Expert

If UCLB considers at any time during the period of this Agreement that the Licensee has failed to comply with its obligations under Clause 6.1 or 6.3, then the matter shall be referred to an independent expert to answer the following questions:

- 6.10.1 whether the Licensee has complied with its obligations under Clause 6.1 or 6.3; and if not
- 6.10.2 what specific action the Licensee should have taken and/or now needs to take ("Specific Action") in order to fulfil such obligations and within what period the Specific Action should be taken ("Action Period").

The independent expert shall be appointed in accordance with the provisions of Schedule 2 and his decision shall be final and binding on the Parties.

# 6.11 Consequences of Expert's Decision

If the expert determines that the Licensee has failed to comply with its obligations under Clause 6.1 or 6.3, and if the Licensee fails to take the Specific Action within the Action Period, UCLB shall be entitled, by giving, at any time within [\*\*\*] ([\*\*\*]) months after the end of that Action Period, not less than [\*\*\*] ([\*\*\*]) months' notice, to (a) convert the licence granted under Clause 2.1.1 into a non-exclusive licence or (b) terminate this Agreement.

# 6.12 Use and sale in United States

The Licensee agrees that for use and sale of the rights under the Patents in the United States, any products embodying the Patents, or produced through use of the Patents, shall be manufactured substantially in the United States, unless a waiver is granted by the NIH. UCLB shall use reasonable efforts, and shall ensure that MEEI use reasonable efforts to assist in the preparation and obtaining of such a waiver, if requested in writing by Licensee and at Licensee's reasonable expense.

# 7. ACCESS TO MEDICINES AND ETHICAL LICENSING

### 7.1 General Diligence

The Licensee agrees to use Diligent Efforts to develop and commercially exploit Licensed Products in a manner consistent with ethical and socially responsible licensing principles, including requiring all Sub-licensees and other parties involved in the development and commercial exploitation of Licensed Products to agree in writing to comply with ethical and socially responsible licensing principles.

# 7.2 Supply to Developing Countries

# 7.2.1 Supply by the Licensee

The Licensee shall use Diligent Efforts to supply the Licensed Products to customers in At-Cost Markets at a Cost-Based Price and to meet market demand for the Licensed Products in those markets.

# 7.2.2 Sub-Licensing in Developing Country markets

If the Licensee is unable to supply the Licensed Product at a Cost-Based Price in any At-Cost Market and to meet market demand for the Licensed Products in those markets, it shall use Diligent Efforts to license one or more Developing Country Manufacturers on Reasonable Developing Country License Terms to manufacture, distribute and sell the Licensed Product at a Cost-Based Price in that At-Cost Market.

# 7.3 Reporting

The Licensee shall keep UCLB regularly updated regarding the Licensee's efforts to supply the Licensed Products in accordance with the requirements outlined in Clauses 7.1 and 7.2.

# 7.4 Step In Rights

- 7.4.1 If at any time UCLB acting reasonably considers that the Licensee is not meeting its obligations under Clauses 7.1 and 7.2 in relation to the supply of the Licensed Products to customers in At-Cost Markets, UCLB may be written notice require the Licensee to seek one or more third parties to develop, commercialise and supply the Licensed Products to customers in At-Cost Markets.
- 7.4.2 If the Licensee following a written requirement from UCLB refuses to grant a sub-license to or is unable to identify a third party to develop, commercialise and supply the Licensed Products to customers in At-Cost Markets, then UCLB notwithstanding the rights granted to the Licensee under this Agreement shall have the right to seek a third party and/ or to grant to a third party a license to manufacture, have manufactured, use, sell, offer for sale and import the Licensed Products for supply in the At-Cost market on Reasonable Developing Country License Terms.

### 8. COMPLIANCE WITH LAWS

# 8.1 General Compliance with Laws

The Licensee will at all times (and will ensure its Affiliates and Sub-licensees) comply with all legislation, rules, regulations and statutory requirements applying to and obtain any consents necessary for its use of the Patents, the Know-how and the Materials, the development, manufacture, and sale of Licensed Products in any country or territory.

# 8.2 Bribery Act

The Licensee shall (and shall procure that any persons associated with it engaged in the performance of this Agreement including its Affiliates and Sub-licensees shall):

8.2.1 comply with all applicable laws and codes of practice relating to anti-bribery and anti-corruption including the Bribery Act 2010 and without prejudice to the foregoing generality, shall not engage in any activity, practice or conduct which would constitute an offence under sections 1, 2 or 6 of the Bribery Act 2010 or do or omit to do any act that will cause or lead UCLB to be in breach of the Bribery Act 2010;

- 8.2.2 comply with UCLB's ethics, anti-bribery and anti-corruption policies as notified to the Licensee from time to time and have, maintain in place and enforce throughout the term of this Agreement adequate procedures to ensure compliance with Clause 8.2.1; and
- 8.2.3 promptly report to UCLB any request or demand for any undue financial or other advantage of any kind received in connection with the performance of this Agreement.

For the purpose of this Clause 8.2, the meaning of adequate procedures and whether a person is associated with another person shall be determined in accordance with the Bribery Act 2010 (and any guidance issued under section 9 of that Act). Breach of this Clause 8.2 shall be deemed a material breach of this Agreement entitling UCLB to terminate under Clause 12.2.1.

### 8.3 Export Control Regulations

The Licensee shall ensure that, in using the Patents, Know-how or Materials and in selling Licensed Products, it and its Affiliates, employees, sub-contractors and Sub-licensees comply fully with any United Nations trade sanctions or EU or UK legislation or regulation, from time to time in force, which impose arms embargoes or control the export of goods, technology or software, including weapons of mass destruction and arms, military, paramilitary and security equipment and dual-use items (items designed for civil use but which can be used for military purposes) and certain drugs and chemicals.

### 9. INTELLECTUAL PROPERTY

### 9.1 Obtain and Maintain the Patents

- 9.1.1 The Licensee shall be responsible for the drafting, filing, prosecution and maintenance of all of the Patents at the Licensee's cost and expense. Subject to resource availability, UCLB shall use commercially reasonable efforts to provide such assistance as the Licensee may request to prosecute and maintain the Patents[\*\*\*] that may be incurred in providing such assistance.
- 9.1.2 The Patents will be filed, prosecuted and maintained in the countries and territories set out in Schedule 4. The Licensee shall notify UCLB of any decisions as to which (if any) additional countries to file and maintain Patents in.
- 9.1.3 The Licensee shall consult with UCLB in relation to all material changes to the patent claims or specifications that would have the effect of reducing or limiting the scope of the Patents, and not make any such changes without the prior written consent of UCLB. Such consent shall not be unreasonably withheld or delayed provided that UCLB has been given as much notice as is practicable, and in any event no less than [\*\*\*] days' notice (or such shorter period for response dictated by the relevant patent office) of such proposed changes, and has been given an opportunity to file divisionals, continuations and/or such other types of protection to cover any claims or subject matter that the Licensee intends to remove from the

scope of the Patents. If UCLB fails to respond before the end of the [\*\*\*] day period (or such shorter period for response dictated by the relevant patent office), the Licensee may proceed with the proposed changes to the patent claims or specifications. The Licensee will ensure that UCLB receives copies of all correspondence to and from Patent Offices in respect of the Patents, including copies of all documents generated in or with such correspondence, and shall be given reasonable notice (or such shorter period for response dictated by the relevant patent office) of and the opportunity to participate in any conference calls or meetings with the Licensee's patent attorneys in relation to the drafting, filing, prosecution and maintenance of the Patents, so that UCLB may be continuously informed of progress with the drafting, filing, prosecution and maintenance of the Patents. Such involvement of UCLB under this Clause 9.1.3 shall be at UCLB's cost and expense.

- 9.1.4 If the Licensee wishes to abandon any application contained with the Patents or not to maintain any such Patent, it shall give [\*\*\*] ([\*\*\*]) months' prior written notice to UCLB and on the expiry of such notice period the licences of the relevant Patents granted to the Licensee under this Agreement shall cease.
- 9.1.5 In the event that any of rights granted hereunder become non-exclusive, responsibility for the drafting, filing, prosecution and maintenance of all of the Patents shall revert to UCLB.

### 9.2 Infringement of the Patents, the Know-how and/or the Materials

- 9.2.1 Each Party shall promptly give to the other Party and MEEI written notice if it becomes aware of any infringement or potential infringement of any of the Patents or any unauthorised use of the Know-how or the Materials or any challenge to the validity or ownership of the Patents, the Know-how or the Materials and the Parties shall consult with each other and MEEI to decide the best way to respond to such infringement, unauthorised use or challenge.
- 9.2.2 The Licensee shall have the primary obligation and right to take action against any third party alleged to be infringing the Patents or making unauthorised use of the Know-how or the Materials and to defend the Patents against challenges to validity or ownership at its sole expense, provided that:
  - (a) the Licensee, UCLB and MEEI, in cooperation with the NIH, shall use their commercially reasonable efforts to eliminate the infringement without litigation. If the efforts of the Licensee, UCLB and MEEI are not successful in eliminating the infringement within [\*\*\*] ([\*\*\*]) days after the infringer has been formally notified of the infringement by the Licensee, the Licensee shall have the right, after consulting with the MEEI, NIH and UCLB, to commence suit on its own account;

- (b) UCLB shall procure that MEEI shall and that MEEI shall procure that the NIH shall on the Licensee's or UCLB's request cooperate with the Licensee in such action [\*\*\*], provided that the Licensee shall not be required under this Clause 9.2.2 to [\*\*\*]; and
- (c) UCLB shall on the Licensee's request cooperate with the Licensee in such action [\*\*\*]; and
- (d) the Licensee shall be solely responsible for the conduct of the action or for settlement thereof and shall be entitled to all damages received from such action, subject to Clause 9.2.4.
- 9.2.3 Before starting or defending or settling any legal action under Clause 9.2.2, the Licensee shall consult with UCLB as to the advisability of the action or defence or settlement, its effect on the good name of UCLB, the public interest, and how the action or defence should be conducted.
- 9.2.4 The Licensee shall [\*\*\*] in such action or defence.
- 9.2.5 UCLB shall if reasonably requested by the Licensee agree to be joined in any suit to enforce such rights or will take such action in its own name [\*\*\*] and shall have the right to be separately represented by its own counsel [\*\*\*]. Notwithstanding the foregoing, [\*\*\*].
- 9.2.6 UCLB shall procure that MEEI shall and that MEEI shall procure that the NIH shall if reasonably requested by UCLB or the Licensee agree to be joined in any suit to enforce such rights or will take such action in its or their own name(s) [\*\*\*]. Notwithstanding the foregoing, [\*\*\*], provided that [\*\*\*].
- 9.2.7 If, within [\*\*\*] of the Licensee or UCLB giving to the other and MEEI written notice or receiving written notice from the other or MEEI of any potential infringement of the Patents, the Licensee and UCLB are both unsuccessful in persuading the alleged infringer to desist or fail to initiate an infringement action, MEEI shall have the right, at its sole discretion, to prosecute such infringement under its sole control and [\*\*\*].

# 9.3 Infringement of Third Party Rights

9.3.1 If any warning letter or other notice of infringement is received by a Party, or legal suit or other action is brought against a Party, alleging infringement of third party rights in the manufacture, use or sale of any Licensed Product or use of any Patents, Know-how or Materials, that Party shall promptly provide full details to the other Party, and Licensee and UCLB shall discuss the best way to respond with MEEI.

9.3.2 The Licensee shall have the right but not the obligation to defend such suit to the extent it relates to Licensee's or its Affiliates' or Sub-licensee's activities and shall have the right to settle with such third party, provided that [\*\*\*]. In the event that the Licensee, Affiliates or Sub-licensees do not take forward an action, UCLB shall have the right, at its sole discretion, to defend such suit under its sole control and [\*\*\*].

# 10. WARRANTIES AND LIABILITY

# 10.1 Warranties by UCLB

UCLB warrants and undertakes as follows to its reasonable knowledge and without having undertaken any due and careful enquires whether specific or general in nature:

- 10.1.1 It, MEEI and NIH are the owners of the Patents;
- it has the authority to grant the licences under this Agreement; and.
- 10.1.3 so far as it is aware (having made no enquiry of any third parties or conducted any freedom to operate searches), use and exploitation of the Patents will not infringe the intellectual property rights of any third party.

### 10.2 Warranties by the Licensee

The Licensee warrants and undertakes that:

- it has the right and authority to enter into this Agreement;
- so far as it is aware (having made no enquiry of any third parties), use and exploitation of the Patents will not infringe the intellectual property rights of any third party;
- 10.2.3 neither it nor any of its Affiliates is currently researching, developing, marketing, selling or otherwise commercialising any Competing Product ("Competing Activities"), nor has any of them entered into an agreement with any other person with respect to any Competing Activities; and
- 10.2.4 it shall notify UCLB if it or any of its Affiliates or its Sub-licensees commences any Competing Activities or enters into an agreement with any other person with respect to any Competing Activities.

# 10.3 Acknowledgements

The Licensee acknowledges that:

- the inventions claimed in the Patents, and the Know-how and the Materials are at an early stage of development. Accordingly, specific results cannot be guaranteed and any results, materials, information or other items (together "Delivered Items") provided under this Agreement are provided "as is" and without any express or implied warranties, representations or undertakings. As examples, but without limiting the foregoing, UCLB does not give any warranty that Delivered Items are of merchantable or satisfactory quality, are fit for any particular purpose, comply with any sample or description, or are viable, uncontaminated, safe or non-toxic.
- 10.3.2 UCLB has not performed any searches or investigations into the existence of any third party rights that may affect any of the Patents, Know-how or Materials or the use and exploitation of any of the Patents, Know-how or Materials

#### 10.4 No Other Warranties

- 10.4.1 Each of the Parties acknowledges that, in entering into this Agreement, it does not do so in reliance on any representation, warranty or other provision except as expressly provided in this Agreement, and any conditions, warranties or other terms implied by statute or common law are excluded from this Agreement to the fullest extent permitted by law.
- 10.4.2 Without limiting the scope of Clause 10.4.1, UCLB does not make any representation nor give any warranty or undertaking:
  - (a) express or implied, including, without limitation, any implied warranties of merchantability or of fitness for a particular purpose with respect to any Patent, trademark, software, non-public or other information, or tangible research property, licensed or otherwise provided to the Licensee hereunder and hereby disclaims the same;
  - (b) as to the efficacy or usefulness of the Patents, Know-how or Materials; or
  - (c) whatsoever with regard to the scope of any of the Patents or that any of the Patents is or will be valid or (in the case of an application) will proceed to grantor that such Patents may be exploited by the Licensee, Affiliate or Sub-licensee without infringing other patents; or
  - (d) that the Materials or the methods used in making or using the Materials are free from liability for patent infringement; or
  - (e) that the use of any of the Patents, Know-how or Materials Licensed Technologies, the manufacture, sale or use of the Licensed Products, or the exercise of any of the rights granted under this Agreement will not infringe any intellectual property or other rights of any other person; or

- (f) that the Know-how or any other information communicated by UCLB to the Licensee under or in connection with this Agreement will produce Licensed Products of satisfactory quality or fit for the purpose for which the Licensee intended or that any product will not have any defect, latent or otherwise, and whether or not discoverable by inspection; or
- (g) as imposing any obligation on UCLB to bring or prosecute actions or proceedings against third parties for infringement or to defend any action or proceedings for revocation of any of the Patents; or
- (h) as imposing any liability on UCLB in the event that any third party supplies Licensed Products to customers located in the Territory; or
- that there will be no similar or competitive products or services manufactured, used, sold or supplied by any third party in the Territory.

### 10.5 Responsibility for Development of Licensed Products

The Licensee shall be exclusively responsible for its and its Affiliates' and Sub-licensees' use of the Patents, Know-how and Materials, the technical and commercial development and manufacture of Licensed Products and for incorporating any modifications or developments thereto that may be necessary or desirable, for all Licensed Products sold or supplied, notwithstanding any consultancy services or other contributions that UCLB and/or UCL may provide in connection with such activities.

# 10.6 Indemnity

The Licensee shall indemnify each of UCLB and UCL, and each of their respective officers, directors, Council members, employees and representatives (together, the "Indemnitees") against all third party Claims that may be asserted against or suffered by any of the Indemnitees and which relate to:

- 10.6.1 the use by the Licensee or any of its Affiliates or Sub-licensees of any of the Patents, Know-how or Materials; or
- the development, manufacture, use, marketing or sale of, or any other dealing in, any of the Licensed Products, by or on behalf of the Licensee or any of its Affiliates or Sub-licensees, or subsequently by any customer or any other person, including claims based on product liability laws.

The indemnity given by the Licensee to each Indemnitee under this Clause 10.6 will not apply to any third party Claim to the extent that it is attributable to the negligence, gross negligence, reckless misconduct or intentional misconduct of any Indemnitee.

# 10.7 Indemnification and Defence

- Licensee shall indemnify, defend and hold harmless MEEI and its trustees, officers, medical and professional staff, employees and agents and their respective successors, heirs and assigns (the "MEEI Indemnitees"), against any liability, damage, loss or expense (including reasonable attorney's fees and expenses of litigation) incurred by or imposed upon the MEEI Indemnitees or any one of them in connection with any third party claims, suits, actions, demands or judgments: arising out of any theory of product liability (including, but not limited to, actions in the form of contract, tort, warranty, or strict liability) concerning any product, process or service made, used or sold or any right or license granted under this Agreement.
- 10.7.2 Licensee's indemnification under this Clause 10.7 shall not apply to liability, damage, loss or expense to the extent that it is directly attributable to the negligent activities, reckless misconduct or intentional misconduct of the MEEI Indemnitees.
- 10.7.3 Licensee agrees, at its own expense, to provide attorneys reasonably acceptable to MEEI to defend against any actions brought or filed against any party indemnified hereunder with respect to the subject of indemnity contained herein, whether or not such actions are rightfully brought.
- 10.7.4 This Clause 10.7 shall survive expiration or termination of this Agreement.

# 10.8 Limitations of Liability

- 10.8.1 To the extent that UCLB or any of its Affiliates has any liability in contract, tort, or otherwise under or in connection with this Agreement, including any liability for breach of warranty, their liability shall be limited in accordance with the following provisions of this Clause 10.8.
- The aggregate liability of UCLB and any of its Affiliates shall be limited to the total income that UCLB has received from the Licensee pursuant to this Agreement (but excluding any other costs or expenses associated with drafting, filing, prosecuting, maintaining or defending any Patents or providing any assistance to the Licensee) during the period of [\*\*\*] ([\*\*\*]) years preceding the date on which the liability arises, or fifty thousand pounds (£50,000) sterling, whichever is the higher.
- 10.8.3 The liability of the Licensee to UCLB shall be limited to the limit of its insurance as set out in Clause 10.9.1, except that in the case of product liability, the liability of the Licensee under this Agreement shall be unlimited.
- In no circumstances shall either Party or any Indemnitee be liable for any loss, damage, costs or expenses of any nature that is (a) of an indirect, special or consequential nature or (b) any loss of profits (whether direct or indirect), revenue, business opportunity or goodwill, which arises directly or indirectly from that Party's breach or non performance of this Agreement, or negligence in the performance of

this Agreement or from any liability arising in any other way out of the subject matter of this Agreement even if the Party bringing the claim has advised the other Party or the relevant Indemnitee of the possibility of those losses arising, or if such losses were within the contemplation of the Parties or the Indemnitee.

Nothing in this Agreement excludes either Party's liability to the extent that it may not be so excluded under applicable law, including any such liability for death or personal injury caused by that Party's negligence, or liability for fraud or fraudulent misrepresentation.

# 10.9 Insurance: UCLB Requirements

- The Licensee shall take out with a reputable insurance company and maintain at all times during the term of this Agreement public and product liability and professional indemnity insurance including against all loss of and damage to property (whether real, personal or intellectual) and injury to persons including death arising out of or in connection with this Agreement and the Licensee's and its Affiliates' and Sub-licensees' use of the Patents, Know-how or Materials and use, sale of or any other dealing in any of the Licensed Products. Such insurances may be limited in respect of one claim provided that such limit must be at least [\*\*\*] pounds ( $\mathfrak{L}$ [\*\*\*]) sterling, unless the Licensee commences any business in manufacturing, distribution, supply or otherwise make available to the public any products, in which case such limit must be at least [\*\*\*] pounds ( $\mathfrak{L}$ [\*\*\*]) sterling. Such insurance shall continue to be maintained for a further [\*\*\*] years from the end of this Agreement.
- 10.9.2 The Licensee will produce to UCLB at all times upon demand proof that the insurance cover required pursuant to Clause 10.9.1 is in force and evidence that all premiums have been paid up to date. If UCLB becomes aware that the Licensee has failed to maintain the insurance required pursuant to Clause 10.9.1, UCLB may effect such insurance and the Licensee will reimburse UCLB for the reasonable cost of effecting and maintaining such insurance on demand.

# 11. INSURANCE: MEEI REQUIREMENTS

Beginning no later than the time any Licensed Products are being commercially distributed or sold (other than for the purpose of obtaining regulatory approvals) by Licensee or by a Sub-licensee, affiliate or agent of Licensee, Licensee shall, at its own cost and expense procure and maintain Commercial General Liability (CGL) insurance or other coverage acceptable to MEEI in amounts not less than \$[\*\*\*] per incident or occurrence and \$[\*\*\*] annual aggregate and naming the MEEI Indemnitees as additional insureds. Such CGL or other insurance shall provide:

- (a) Product liability coverage, and
- (b) Contractual liability coverage for Licensee's indemnification under Clause 10.7 of this Agreement.
- 11.1.2 If Licensee elects to self-insure all or parts of the limits described above (including deductibles or retentions which are in excess of \$[\*\*\*] annual aggregate) such self-insurance program must be acceptable to MEEI and CRICO. The minimum amount of insurance coverage required under this Clause 11.1 shall not be construed to create a limit of Licensee's liability with respect to its indemnification under Clause 10.7 of this Agreement. Licensee shall provide MEEI with written evidence of such insurance upon request of MEEI. Licensee shall provide MEEI with written notice at least [\*\*\*] ([\*\*\*]) days prior to the cancellation, non-renewal or material change in such insurance, if:
  - (a) Licensee does not obtain replacement insurance providing comparable coverage within such [\*\*\*] ([\*\*\*]) day period, MEEI shall have the right to terminate this Agreement effective at the end of such [\*\*\*] ([\*\*\*]) days without notice of any additional waiting period.
- 11.1.3 Licensee shall maintain such CGL or other insurance during:
  - (a) the period that any Licensed Products are being commercially distributed or sold (other than for the purpose of obtaining regulatory approvals) by Licensee or by a Sub-licensee, affiliate or agent of Licensee;
  - (b) reasonable period after the period referred to in Clause 11.1.3 (a) above, which in no event shall be less than [\*\*\*] ([\*\*\*]) years.
- 11.1.4 This Clause 11.1 shall survive expiration or termination of this Agreement.

### 12. DURATION AND TERMINATION

# 12.1 Commencement and Expiry

This Agreement and the licences granted hereunder, shall come into effect on the Commencement Date and, unless terminated earlier in accordance with this Clause 12, the licences granted hereunder shall continue in force on a country by country basis until the later of the last payment obligation of Licensee expires under this Agreement. Upon such expiry, Licensee's licenses under this Agreement shall become full-paid, perpetual and irrevocable.

# 12.2 Early Termination

Each Party (the "Terminating Party") may terminate this Agreement at any time by notice in writing to the other Party ("Other Party"), such notice to take effect as specified in the notice:

12.2.1 if the Other Party is in material breach of this Agreement and, in the case of a breach capable of remedy within thirty (30) days, the breach is not remedied within thirty (30) days of the Other Party receiving notice specifying the breach and requiring its remedy; or

### 12.2.2 if:

- (a) the Other Party becomes insolvent or unable to pay its debts as and when they become due;
- (b) an order is made or a resolution is passed for the winding up of the Other Party (other than voluntarily for the purpose of solvent amalgamation or reconstruction);
- (c) a liquidator, administrator, administrative receiver, receiver or trustee is appointed in respect of the whole or any part of the Other Party's assets or business;
- (d) the Other Party makes any composition with its creditors;
- (e) the Other Party ceases to continue its business; or
- (f) any event analogous to the events referred to in paragraphs (a) to (e) above occurs in any other jurisdiction.
- 12.3 UCLB may terminate this Agreement by giving written notice to the Licensee, such termination to take effect forthwith or as otherwise stated in the notice:
- 12.3.1 if there is any change of Control of the Licensee involving the categories of persons or Affiliates of persons prohibited by Clause 2.3; or
- 12.3.2 the Licensee is in persistent breach of the Agreement and where the Parties have failed to agree a mechanism to remedy the persistent nature of such breaches within a reasonable period following UCLB notifying the Licensee of the persistent breach and requesting that the Licensee enters into discussions with UCLB as to mechanisms for remedying the persistent breaches or if the Parties have agreed a mechanism to remedy the persistent breach but that mechanism if not fully complied with by the Licensee; or
- 12.3.3 if the Licensee shall enter into any sub-licence with any of the categories of persons or Affiliates of persons prohibited by Clause 2.3 which may, adversely affect UCL's and/or UCLB's reputation.
- 12.4 A Party's right of termination under this Agreement, and the exercise of any such right, shall be without prejudice to any other right or remedy (including any right to claim damages) that such Party may have in the event of a breach of contract or other default by the other Party.

# 12.5 Consequences of Termination

- 12.5.1 Upon expiry of the period of this Agreement, and subject to all royalties and any other sums due to UCLB under this Agreement having been duly paid, the Licensee shall have a fully paid up licence to the Patents, the Know-how and the Materials of the same scope as set forth in Clauses 2.1.1 and 2.1.2 without any further obligation to pay any further sums to UCLB under Clause 5. Notwithstanding the foregoing the Licensee acknowledges that once each Patent expires or is abandoned or withdrawn or allowed to lapse in any country or territory, third parties in that country or territory will be entitled to use the inventions claimed in the Patent and that accordingly the licence granted to the Licensee under Clause 2.1.1 will no longer be exclusive in that country or territory.
- 12.5.2 Upon termination of this Agreement by UCLB under Clause 12.2.1 (for Licensee's uncured material breach) or under Clause 12.3:
  - (a) the Licensee and its Affiliates and Sub-licensees shall be entitled to sell, use or otherwise dispose of (subject to payment of royalties under Clause 5) any unsold or unused stocks of the Licensed Products for a period of six (6) months following the date of termination:
  - (b) subject to paragraph (a) above, any license that has not become fully paid-up in accordance with Clause 12.1 shall terminate and the Licensee and its Affiliates (and subject to Clause 2.3, its Sub-licensees) shall no longer be licensed to use or otherwise exploit the Patents and/or the Know-how and/or the Materials, in so far and for as long as any of the Patents remains in force and the Know-how remains confidential;
  - (c) the Licensee shall consent to the cancellation of any formal licence granted to it, or of any registration of it in any register, in relation to any of the Patents;
  - (d) the Licensee will, promptly on UCLB's request, provide (and will ensure that its patent agents provide) to UCLB all information, documentation and assistance (including executing documents) which UCLB may reasonably require to enable it to continue with the drafting, filing, prosecution and maintenance of the Patents;
  - (e) except as set out in Clause 2.3, all sub-licences of the Patents and/or the Know-how and/or the Materials granted by the Licensee pursuant to this Agreement will automatically terminate;
  - (f) each Party shall upon the written request of the other Party, return or destroy any documents or other materials that are in its or its Affiliates possession or under its or their control and that contain the other Party's Confidential Information.

- 12.6 If Licensee may terminate this Agreement under Clause 12.2.1 (for UCLB or its Affiliates uncured material breach), then Licensee may elect, in lieu of terminating the entire Agreement, to have all licenses granted under this Agreement survive, subject to Licensee's fulfilment of [\*\*\*] percent ([\*\*\*]%) of its payment obligations under Clause 5 after what would have been the effective date of such termination.
- 12.7 Upon termination of this Agreement for any reason, the provisions of Clauses 1, 2.3, 2.5, 3.2 to 3.6, 5 (in respect of amounts paid and payable to UCLB in respect of the period up to an including the date of termination) 6.6, 8, 10, 12.5, 12.6, 12.7 and 13 of this Agreement shall remain in force

### 13. GENERAL

# 13.1 Force Majeure

- 13.1.1 Any delays in or failure of performance by either Party under this Agreement will not be considered a breach of this Agreement and if and to the extent that such delay or failure is caused by occurrences beyond the reasonable control of that Party including acts of God; acts, regulations and laws of any government; strikes or other concerted acts of workers; fire; floods; explosions; riots; wars; rebellion; and sabotage; and any time for performance hereunder will be extended by the actual time of delay caused by any such occurrence.
- 13.1.2 If either Party is prevented from carrying out its obligations:
  - (a) under this Agreement for a continuous period of [\*\*\*] ([\*\*\*]) months the other Party may terminate this Agreement on giving [\*\*\*] ([\*\*\*]) days prior written notice provided always that at the date upon which termination becomes effective the Party which was prevented from carrying out its obligations under this Agreement remains so prevented.

#### 13.2 Amendment

This Agreement may only be amended in writing signed by duly authorised representatives of UCLB and the Licensee.

### 13.3 Assignment and Third Party Rights

13.3.1 Subject to Clause 13.3.3, the Licensee shall not assign, mortgage, charge or otherwise transfer any rights or obligations under this Agreement, nor any of the Patents, Know-how or Materials, without the prior written consent of UCLB.

- 13.3.2 UCLB may assign all its rights and obligations under this Agreement together with its rights in the Patents, Know-how and Materials to any third party.
- 13.3.3 The Licensee, subject to obtaining the consent of UCLB which shall not be unreasonably withheld or delayed (except in relation to those categories of persons or Affiliates of persons prohibited by Clause 2.3), may assign all its rights and obligations under this Agreement together with its rights in the Patents, Know-how and Materials to any third party to which it transfers all or substantially all of its assets or business, provided that the assignee undertakes to UCLB to be bound by and perform the obligations of the assignor under this Agreement. However the Licensee shall not have such a right to assign this Agreement if it is insolvent.

# 13.4 Waiver

Any waiver given under or in relation to this Agreement shall be in writing and signed by or on behalf of the relevant Party. No failure or delay on the part of either Party to exercise any right or remedy under this Agreement shall be construed or operate as a waiver thereof, nor shall any single or partial exercise of any right or remedy preclude the further exercise of such right or remedy.

#### 13.5 Invalid Clauses

If any provision or part of this Agreement is held to be invalid, amendments to this Agreement may be made by the addition or deletion of wording as appropriate to remove the invalid part or provision but otherwise retain the provision and the other provisions of this Agreement to the maximum extent permissible under applicable law.

### 13.6 No Agency

Neither Party shall act or describe itself as the agent of the other, nor shall it make or represent that it has authority to make any commitments on the other's behalf.

### 13.7 Interpretation

In this Agreement:

- 13.7.1 the headings are used for convenience only and shall not affect its interpretation; references to persons shall include incorporated and unincorporated persons; references to the singular include the plural and vice versa; and references to the masculine include the feminine;
- 13.7.2 references to Clauses and Schedules mean clauses of, and schedules to, this Agreement;
- 13.7.3 references in this Agreement to termination shall include termination by expiry;

- 13.7.4 where the word "including" is used it shall be understood as meaning "including without limitation";
- 13.7.5 any reference to any English law term for any action, remedy, method or judicial proceeding, legal document, legal status, court, official or any legal concept or thing shall in respect of any jurisdiction other than England be deemed to include what most nearly approximates in that jurisdiction to the English law term;
- 13.7.6 where there is any conflict or inconsistency between the main body of this Agreement and any of the schedules, then the main body of the Agreement shall prevail;
- 13.7.7 time shall be of the essence in relation to the performance of the Licensee's obligations under this Agreement; and
- 13.7.8 any reference to the sale of a Licensed Product by the Licensee or its Affiliates or Sub-licensees will be taken to include any supply or other disposal of Licensed Products, and the term sold shall be construed accordingly.

### 13.8 Notices. Addresses for Service

- 13.8.1 Any notice to be given under this Agreement shall be in English, in writing and shall be delivered by first class recorded delivery mail (if sent to an inland address) or by international courier (if sent to an address outside of the United Kingdom), to the address of the relevant Party set out at the head of this Agreement, or such other address as that Party may from time to time notify to the other Party in accordance with this Clause 13.8.
- 13.8.2 Notices sent as above shall be deemed to have been received [\*\*\*] ([\*\*\*]) working day after the day of posting in the case of delivery inland first class recorded delivery mail, or [\*\*\*] ([\*\*\*]) working days after the date of collection by the international courier.

# 13.9 Law and Jurisdiction

The validity, construction and performance of this Agreement, and any contractual and non-contractual claims arising hereunder, shall be governed by English law and shall be subject to the exclusive jurisdiction of the English courts to which the Parties hereby submit, except that a Party may seek an interim injunction (or an equivalent remedy) in any court of competent jurisdiction.

### 13.10 Entire Agreement

This Agreement, including its Schedules, sets out the entire agreement between the Parties relating to its subject matter and supersedes all prior oral or written agreements, arrangements or understandings between them relating to such subject matter. Subject to Clause 10.8.5, the Parties acknowledge that they are not relying on any representation, agreement, term or condition which is not set out in this Agreement.

# 13.11 Third Parties

Except for the rights of UCL, MEEI and NIH as provided in Clause 2.4, the rights of the Indemnitees as provided in Clause 10.6, the rights of MEEI Indemnitees as provided in Clause 10.7, the limitations of liability afforded to the Indemnitees pursuant to Clause 10.8, the rights of MEEI under Clause 11.1.2 and the rights of MEEI and NIH under Clause 9, who may in their own right enforce and rely on the provisions of those Clauses, this Agreement does not create any right enforceable by any person who is not a party to it ("Third Party") under the Contracts (Rights of Third Parties) Act 1999, but this Clause 13.11 does not affect any right or remedy of a Third Party which exists or is available apart from that Act. The Parties may amend, renew, terminate or otherwise vary all or any of the provisions of this Agreement, including Clauses 2.4, 9, 10.6 and 10.7, and 10.8, without the consent of MEEI, NIH and/or the MEEI Indemnitees.

### 13.12 Non-use of Names; Announcements

- 13.12.1 The Licensee shall not use, and shall ensure that its Affiliates and Sub-licensees do not use, the name, any adaptation of the name, any logo, trademark or other device of UCLB, nor of the inventors named on the Patents nor the Principal Investigators in any advertising, promotional or sales materials without prior written consent obtained from UCLB in each case, except that the Licensee may state that it is licensed by UCLB under the Patents.
- 13.12.2 Except as permitted under Clauses 3.4.1 and 6.6, neither Party shall make any press or other public announcement concerning any aspect of this Agreement, or make any use of the name or trade marks of the other Party in connection with or in consequence of this Agreement, without the prior written consent of the other Party.

### 13.13 Escalation

If the Parties are unable to reach agreement on any issue concerning this Agreement or the Project within [\*\*\*] days after one Party has notified the other of that issue, they will refer the matter to the [\*\*\*] in the case of UCLB, and to the [\*\*\*] in the case of the Licensee in an attempt to resolve the issue within the time specified elsewhere in this Agreement in the case of other disputes. Either Party may bring proceedings in a court of competent jurisdiction if the matter has not been resolved within that prescribed period, and either Party may apply to the court for an injunction, whether or not any issue has been escalated under this Clause 13.13.

# **EXECUTED** on the date set out at the head of this Agreement.

For and on behalf of	For and on behalf of
UCL Business PLC	MEIRAGTX UK II LIMITED
/s/ Anne Lane	/s/ Richard Giroux
Signed	Signed
Anne Lane	Richard Giroux
Print name	Print name
Executive Director	Chief Operating Officer
Title	Title
10/8/17	August 16, 2017
Date	Date

# SCHEDULE 1 LICENSED TECHNOLOGY

Part A: The Patents
[***]
Part B: The Know-how
[***]
Part C: The Materials
[***]

# SCHEDULE 2 APPOINTMENT OF EXPERT

If either Party wishes to appoint an independent expert (the "Expert") to determine any matter pursuant to any Clause of this Agreement, the following procedures will apply:

- 1. The Party wishing to appoint the Expert ("the Appointing Party") will serve a written notice on the other Party ("the Responding Party"). The written notice will specify the Clause pursuant to which the appointment is to be made and will contain reasonable details of the matter(s) which the Appointing Party wishes to refer to the Expert for determination
- 2. The Parties shall within [\*\*\*] ([\*\*\*]) days following the date of the Appointing Party's written notice use all reasonable efforts to agree who is to be appointed as the Expert to determine the relevant matter(s). If the Parties are unable to agree upon the identity of the Expert within that timescale, the Expert shall be appointed by the President (for the time being) of the Licensing Executives Society Britain and Ireland upon written request of either Party.
- 3. Each Party will within [\*\*\*] ([\*\*\*]) days following appointment of the Expert, prepare and submit to the Expert and the other Party a detailed written statement setting out its position on the matter(s) in question and including any proposals which it may wish to make for settlement or resolution of the relevant matter.
- 4. Each Party will have [\*\*\*] ([\*\*\*]) days following receipt of the other Party's written statement to respond in writing thereto. Any such response will be submitted to the other Party and the Expert.
- 5. The Expert will if he/ she deems appropriate be entitled to seek clarification from the Parties as to any of the statements or proposals made by either Party in their written statement or responses. Each Party will on request make available all information in its possession and shall give such assistance to the Expert as may be reasonably necessary to permit the Expert to make his/ her determination.
- 6. The Expert will issue his/ her decision on the matter(s) referred to him/ her in writing as soon as reasonably possible, but at latest within [\*\*\*] ([\*\*\*]) months following the date of his/ her appointment. The Expert's decision shall (except in the case of manifest error) be final and binding on the Parties.
- 7. The Expert will at all times act as an independent and impartial expert and not as an arbitrator.
- 8. The Expert's charges will be borne as he/ she determines in his written decision.

### **SCHEDULE 3**

### **DEFINITION OF TOBACCO INDUSTRY FUNDING (REVISED 2009)**

### FROM THE CANCER RESEARCH UK CODE OF PRACTICE ON TOBACCO INDUSTRY FUNDING TO UNIVERSITIES.

http://www.cancerresearchuk.org/science/funding/terms-conditions/funding-policies/policy-tobacco/

A tobacco company is defined for the purposes of this policy as one that:

- Derives over 5% of revenues from manufacturing tobacco products;
- · Derives 15%+ of revenues from the manufacture of products necessary for the production of tobacco products;
- Derives 15% of revenues from the sale of tobacco products (and has 30 or more staff);
- Owns a tobacco company (the company owns 50% or more of a tobacco company);
- Is more than 50% owned by a company with tobacco involvement.

The following do not constitute tobacco industry funding for the purposes of this Code:

- legacies from tobacco industry investments (provided these are sold on immediately)
- funding from a trust or foundation no longer having any connection with the tobacco industry even though it may bear a name that (for historical reasons) has tobacco industry associations.

# **SCHEDULE 4**

# LIST OF COUNTRIES AND TERRITORIES FOR PATENTS

# SCHEDULE 5

# INITIAL DEVELOPMENT PLAN

[\*\*\*]

# LICENCE AGREEMENT

between

**UCL Business Plc** 

and

MeiraGTx UK II Limited

and

MeiraGTx Limited

**Dated: 15 March 2018** 

Ref:

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2018

THIS AGREEMENT is made 15 March,

### BETWEEN:

(1) **UCL BUSINESS PLC**, a company incorporated in England and Wales under company registration number 02776963 whose registered office is The Network Building, 97 Tottenham Court Road, London W1T 4TP ("UCLB");

ani

- (2) **MEIRAGTX UK II LIMITED, (FORMERLY ATHENA VISION LIMITED)**, a company incorporated in England and Wales with registered number 09348737 and having its registered office at 92 Britannia Walk, London, United Kingdom, N1 7NQ (the "Licensee"); and
- (3) **MEIRAGTX LIMITED (FORMERLY KADMON GENE THERAPY HOLDINGS LIMITED),** a company incorporated in England and Wales with registered number 09501998 and having its registered office at 92 Britannia Walk, London, United Kingdom, N1 7NQ ("Meira").

### WHEREAS:

- A. University College London ("UCL"), through the Principal Investigators, has developed certain technology and owns certain intellectual property rights relating to a gene therapy for [\*\*\*], including the Patents, the Know-how and the Materials.
- B. UCL has assigned to UCLB all of its right, title and interest in and to such property.
- C. The Licensee wishes to acquire rights under the Patents and to use the Know-how and the Materials for the development and commercialisation of Licensed Products in the Field and in the Territory, all in accordance with the provisions of this Agreement.
- D. The Licensee aims to develop and commercialize the Licensed Product in the Field and in the Territory.
- E. Meira wishes to issue shares in the capital of Meira in consideration for the grant of rights set out in this Agreement and is a party to this Agreement solely for this purpose.
- F. It is the policy of UCLB that its activities in licensing intellectual property take into consideration ethical and socially responsible licensing principles, including ensuring that Licensed Products are made available to fulfil unmet needs in Developing Countries, and the Licensee acknowledges and agrees to carry out its activities under this Agreement in a manner which complies with ethical and socially responsible licensing principles and which is designed to fulfil such needs, all in accordance with the provisions of this Agreement.

### NOW IT IS AGREED as follows:

### 1. **DEFINITIONS**

**1.1** In this Agreement:

**Agreement** means this agreement (including the Schedules);

Affiliate in relation to a Party, means any entity or person that Controls, is Controlled by, or is under common Control with that Party;

**At-Cost Markets** means those markets in Developing Countries [\*\*\*];

Claims means all demands, claims and liability (whether criminal or civil, in contract, tort or otherwise) for losses, damages, costs and expenses of any nature whatsoever and all costs and expenses (including legal costs) incurred in connection therewith;

**Commencement Date** means the date of this Agreement;

Commercial Third Party means a commercial entity that is not a Party of this Agreement;

**Competing Product** means any product, whether ready for marketing or in development that competes, or is likely to compete once developed, with any Licensed Product;

Confidential Information means the Know-how, the Materials and all other technical or commercial information that:

- a) in respect of information provided in documentary form or by way of a model or in other tangible form, at the time of provision is marked or otherwise designated to show expressly that it is imparted in confidence or which a reasonable person would expect to be confidential; and
- b) in respect of information that is imparted orally, any information that the Disclosing Party or its representatives informed the Receiving Party at the time of disclosure or which a reasonable person would expect to be confidential;

Consideration Shares means the Convertible Preferred C Shares of £0.00001 each in the capital of Meira to be allotted and issued to UCLB in accordance with Clause 4.1.2(a).

**Control** means direct or indirect beneficial ownership of 50% (or, outside a Party's home territory, such lesser percentage as is the maximum permitted level of foreign investment) or more of the share capital, stock or other participating interest carrying the right to vote or to distribution of profits of that Party, as the case may be;

**Cost-Based Price** means, in respect of each Licensed Product, [\*\*\*];

**Developing Country** or **Developing Countries** refers to those countries that are:

- a) [\*\*\*]; and
- b) to the extent not included in a);
  - i) defined as of the Commencement Date [\*\*\*]; and

ii) all other countries that may be mutually agreed to by UCL and Licensee from time to time;

**Developing Country Manufacturer** means a manufacturer of pharmaceutical products that is able to efficiently manufacture (either within or outside the Developing Country in which the At-Cost market exists), distribute and supply the Licensed Product in an At-Cost market at a Cost-Based Price;

**Diligent Efforts** means exerting such efforts and employing such resources as would normally be exerted or employed by [\*\*\*], when utilizing sound and reasonable scientific, medical and business practice and judgment in order to develop the product in a timely manner and generate an economic return to the Parties from its commercialisation;

**Disclosing Party** has the meaning given in Clause 3.3;

**Field** means ocular gene therapy;

**First Commercial Sale** means the first sale to a third party of a Licensed Product in a given regulatory jurisdiction after all regulatory and marketing approvals have been obtained for such Licensed Product in such jurisdiction. A sale shall not be deemed to have occurred if a Licensed Product is provided pursuant to an early access or compassionate use;

**Indemnitees** has the meaning given in Clause 9.7;

**Intellectual Property** means any and all patents, utility models, registered designs, unregistered design rights, copyright, database rights, rights in respect of confidential information, rights under data exclusivity laws, rights under orphan drug laws, rights under unfair competition laws, property rights in biological or chemical materials, extension of the terms of any such rights (including supplementary protection certificates), applications for and the right to apply any of the foregoing registered property and rights, and similar or analogous rights in any part of the Territory;

### Know-how means:

- a) the inventions claimed in the Patents; and
- b) the technical information relating to the inventions claimed in the Patents and data described in the Part B of Schedule 1;

**Licensed Products** means any and all products that are developed, manufactured, used, or sold by or on behalf of the Licensee or its Affiliates or Sub-licensees and which (a) are within (or are manufactured using a process described in) any claim of the Patents; and/or (b) incorporate, or their development or manufacture makes use of, any of the Know-how and/or the Materials;

Licensed Technology means the Patents, the Know-how and the Materials set out in Schedule 1;

**Materials** means any and all of the materials referred to in Part C of Schedule 1;

Net Sales Value means in respect of the Licensed Products after their First Commercial Sale:

- a) the gross invoiced price of Licensed Products sold by the Licensee or its Affiliates or Sub-licensees in arm's length sales of Licensed Products for cash consideration; and/ or
- b) where the sale is not at arm's length and/ or is for or includes a non-cash consideration, or if Licensed Products used or subject to Clause 5.9, disposed of for free by the Licensee or its Affiliates the relevant open market price for the Licensed Product in the country or territory in which the sale, use or disposal takes place or if the relevant open market price is not ascertainable, a reasonable price, assessed on an arm's length basis therefor,

after deduction of all documented:

- normal trade discounts (but excluding early payment discounts) actually granted and any credits actually given for rejected or returned Licensed Products;
- ii) costs of packaging, insurance, carriage and freight, provided in each case that the amounts are separately charged to the purchaser on the relevant invoice;
- iii) deductions for actual bad debt in connection with sales of Licensed Product (provided that Licensee will use Diligent Efforts to obtain payment of such bad debt);
- iv) value added tax or other sales tax; and
- v) import duties or similar applicable government levies charged to the purchaser on the relevant invoice.

provided that such deductions do not exceed reasonable and customary amounts in the markets in which such sales occurred. Sales of Licensed Products between the Licensee and its Affiliates shall not be taken into account for the purposes of calculating "Net Sales Value" unless there is no subsequent sale to a third party in an arm's length transaction for a cash consideration;

Parties means UCLB, the Licensee and Meira, and "Party" shall mean either of them;

Patent Costs means [\*\*\*].

Patents means any and all of the patents and patent applications referred to in Part A of Schedule 1;

**Principal Investigators** means [\*\*\*].

**Reasonable Developing Country Licence Terms** means terms that meet the requirements of both UCL's ethical and socially responsible licensing policy, which is at: (http://www.ucl.ac.uk/enterprise/about/policies/files/Global\_access-final.pdf) and the following principles:

- a) the Licensee shall [\*\*\*];
- b) the Developing Country licence terms [\*\*\*] that shall not [\*\*\*];
- c) if the Developing Country Manufacturer is granted any exclusive rights, the continued grant of those rights shall be conditional upon the Developing Country Manufacturer supplying At-Cost Markets at a Cost-Based Price and meeting market demand in that market; and
- d) the Licensee may impose reasonable conditions, including as to use of trademarks, trade dress, format and pack size, to differentiate the Licensed Product when sold in the At-Cost market from Licensed Products sold in other markets and to prohibit their export into other markets and territories, provided that such conditions or their implementation do not act as an unreasonable barrier to the prompt and efficient supply of Licensed Product in the At-Cost market;

**Receiving Party** means has the meaning given in Clause 3.3;

**Regulatory Exclusivity** means, with respect to a Licensed Product, any exclusive rights or protection which are recognised, afforded or granted by any Regulatory Authority in any country or region with respect to the Licensed Product other than through patent rights;

**Sub-licensee** means any third party (other than an Affiliate) to whom the Licensee grants a sub-licence of its rights under this Agreement in accordance with Clause 2.3;

Territory means Worldwide;

**Valid Claim** means a claim of a patent or patent application that has not been abandoned or allowed to lapse or expired or been held invalid or unenforceable by a court of competent jurisdiction in a final and non-appealable judgment.

### 2. GRANT OF RIGHTS

### 2.1 Licence

UCLB hereby grants to the Licensee and its Affiliates, and the Licensee hereby accepts on its own behalf and on behalf of its Affiliates, subject to the provisions of this Agreement:

- 2.1.1 an exclusive (even as to UCL) licence under the Patents, with the right to sub-license, subject to Clause 2.3, to develop, commercialise, manufacture, have manufactured, use, sell and have sold Licensed Products only in the Field and in the Territory; and
- 2.1.2 an exclusive (even as to UCL) licence to use the Know-how and the Materials, with the right to sub-license, subject to Clause 2.3, to develop, commercialise, manufacture, have manufactured, use, sell and have sold Licensed Products only in the Field and in the Territory.
- 2.2 UCLB shall at the Licensee's request and cost execute such formal licences as may be necessary to enable the Licensee to register the licences granted to it under this Agreement with the Patent Offices in the relevant Territory. Such formal licence will reflect the terms of this Agreement where possible and for the avoidance of doubt if there is a conflict in the terms of such formal licence and this Agreement, the terms of this Agreement shall prevail. The Licensee shall ensure that this Agreement shall not form part of any public record, except where disclosure of the terms of this Agreement are required by applicable law, rule or regulation (including the rules or regulations of a stock exchange upon which the Licensee's shares are sold).

### 2.3 Sub-Licensing

The Licensee shall have the right to grant sub-licences under the licence in Clause 2.1 to its Affiliates or other third parties through one or more levels of Sub-licensees except that the Licensee may not grant such a sub-licence to any person or the Affiliates of any person involved in: the tobacco industry (as defined by the Cancer Research UK Code of Practice on Tobacco Industry Funding to Universities detailed in Schedule 3); arms dealing; gambling operations; the promotion of violence; child labour or any other illegal activity. A grant of any sub-licence shall be conditional on the following:

- (a) The Licensee shall enter into a written agreement with each Sub-licensee and shall ensure that the provisions of each sub-licence are consistent with the provisions of this Agreement, and the Licensee shall ensure that:
  - (i) the sub-licence sets out all the proposed terms agreed between the Licensee and the Sub-licensee, including, in particular, all terms as to remuneration;

- (ii) the Sub-licensee will maintain complete and accurate records in sufficient detail to permit UCLB to confirm the accuracy of the calculation of royalty payments under this Agreement; and
- (iii) the sub-licence imposes obligations of confidentiality on the Sub-licensee which are no less onerous than those set out in Clause 3.3.
- (b) The Licensee shall procure that each Sub-licensee complies fully at all times with the provisions of its sub-licence.
- (c) The Licensee shall be liable for all acts and omissions of its Sub-licensees that, if committed by the Licensee, would constitute a breach of any of the provisions of this Agreement.
- (d) The Licensee shall provide UCLB with a copy of any sub-licence [\*\*\*] ([\*\*\*]) days after execution of such sub-licence, provided that the Licensee may redact confidential or proprietary terms from such copy, including financial terms.
- (e) Each sub-licence shall terminate automatically upon termination of this Agreement for any reason (but not expiry of this Agreement under Clause 10.1) except where:
  - (i) the Sub-licensee was not implicated in or at fault in any circumstances which led to the termination of this Agreement;
  - (ii) the benefit (but not the burden) of the sub-licence agreement is validly assigned to UCLB in writing within [\*\*\*] ([\*\*\*]) days following the date of termination of this Agreement; and
  - (iii) following assignment, the Sub-licensee observes in full the terms of the sub-licence agreement including paying all sums due to the Licensee under the sub-licence agreement directly to UCLB in a timely manner,

in which case the Sub-licensee's rights to use the Patents and the Know-how and/or the Materials shall continue in full force and effect in accordance with the terms of the relevant sub-licence agreement.

### 2.4 Reservation of Rights

.4.1 UCLB reserves for itself and UCL the non-exclusive, irrevocable, worldwide, royalty-free right to:

- (a) Use the Patents and the Know-how and the Materials in the Field solely for academic research, publication and teaching; and
- (b) Grant licences to academic third parties to use the Patents and the Know-how and the Materials solely in academic research collaborations with UCL; and
- (c) Grant licences of the Patents and the Know-how and the Materials to post graduate students of UCL solely for the purpose of conducting a programme of post graduate academic research.

In exercising the rights described in Clause 2.4.1(b) and (c), UCL and UCLB shall comply with the provisions of Clause 3 as regards confidentiality of the Know-how.

- 2.4.2 UCL and UCLB will refer a request from a third party for a licence to use the Patents in clinical trials or for diagnostic purposes involving human subjects to the Licensee, and the Licensee shall liaise directly with such third party.
- 2.4.3 Except for the licences expressly granted by this Clause 2, UCLB grants no rights to the Licensee under this Agreement to or under any intellectual property other than the Patents, the Know-how and the Materials and hereby reserves all rights under the Patents, the Know-how and the Materials outside the Field.
- 2.4.4 Nothing in this Agreement shall limit or otherwise affect UCL's ability to apply for noncommercial grant funding or comply with such grant terms and conditions. In the event that any terms of this Agreement conflicts with the terms of any non-commercial grant funding, the Parties shall negotiate in good faith to amend the terms of this Agreement to allow UCL to access such funding provided that nothing herein shall require the Licensee to agree to alter or modify the scope of the licence granted to it in this Clause 2.

### 2.5 Affiliates

The Licensee shall:

- 2.5.1 ensure that its Affiliates comply fully with the terms of this Agreement;
- 2.5.2 be responsible for any breach of or non-compliance with this Agreement by its Affiliates as if the breach or non-compliance had been a breach or non-compliance by the Licensee;
- 2.5.3 indemnify in accordance with Clause 9.7 each of the Indemnitees against any Claims which are awarded against or suffered by any of the Indemnitees as a result of any breach of or non-compliance with this Agreement by its Affiliates; and

- 2.5.4 ensure that if any Affiliate ceases to be an Affiliate as a result of a change of Control or otherwise, that unless a sub-licence agreement in accordance with Clause 2.3 is entered into with such an Affiliate, such former Affiliate immediately upon such cessation:
  - (a) ceases developing, manufacturing, having manufactured, using, selling and/ or having sold Licensed Products and ceases all use or exploitation of the Licensed Technology, for as long as any of the relevant Patents remains in force and/or the Know-how remains confidential:
  - (b) returns to the Licensee or destroys any documents or other materials in the former Affiliate's possession or under its control and that contain Confidential Information provided under this Agreement relating to the Licensed Technology and/ or Licensed Products;
  - (c) to the extent possible, takes all action necessary to have any product licences, marketing authorisations, pricing and/ or reimbursement approvals (and any applications for any of the foregoing) which relate to Licensed Products transferred into the name of the Licensee.

### 3. KNOW-HOW AND CONFIDENTIAL INFORMATION

### 3.1 Provision of Know-how and Materials

Within [\*\*\*] ([\*\*\*]) days following the Commencement Date, UCLB shall deliver to the Licensee the Materials and a copy of the Know-how.

### 3.2 Confidentiality of Know-how and Materials

The Licensee undertakes that for so long as the Know-how and/or the Materials remains confidential, it shall (and shall ensure that its Affiliates and Sub-licensees) take all reasonable precautions to prevent unauthorised access to the Know-how and the Materials and protect the Know-how and the Materials in the same manner as it (or they) protect(s) its (or their) own proprietary information, and shall not (and shall ensure that its Affiliates and Sub-licensees do not) use the Know-how or the Materials for any purpose, except as expressly licensed hereby and in accordance with the provisions of this Agreement. For the avoidance of doubt, to the extent that any Materials, Know-how or information relating to the Patents falls within the public domain (without any breach of this Agreement or any other obligation of confidentiality), then UCL, the Principal Investigators and UCLB shall be free to use such information without restriction in the same way that any third party would have the freedom to use it.

### 3.3 Confidentiality Obligations

Each Party ("Receiving Party") undertakes:

- 3.3.1 to maintain as secret and confidential all Confidential Information obtained from, in the case of UCLB, the Licensee or Meira as applicable, and in the case of the Licensee and Meira, UCLB ("Disclosing Party") in the course of or in anticipation of this Agreement and to respect the Disclosing Party's rights therein;
- 3.3.2 to use such Confidential Information only for the purposes of or as permitted by this Agreement; and
- 3.3.3 subject to Clause 3.4, to disclose such Confidential Information only to those of its employees, contractors, Affiliates, and Sub-licensees (if any) to whom and to the extent that such disclosure is reasonably necessary for the purposes of this Agreement.

### 3.4 Permitted Disclosure

- 3.4.1 The Licensee shall have the right to disclose Confidential Information received from UCLB to:
  - (a) potential or actual customers of Licensed Products to the extent reasonably necessary to promote the sale or use of Licensed Products and provided that the customer has agreed to confidentiality provisions at least as restrictive as set forth herein;
  - (b) to existing or potential Sub-licensees, collaborators, investors or lenders provided that such third parties have agreed to confidentiality provisions at least as restrictive as set forth herein; and
  - (c) to its Board of Directors (or similar governing body) and its counsel, accountants and other professional advisers.

### 3.5 Exceptions to Obligations

The provisions of Clause 3.3 shall not apply to Confidential Information which the Receiving Party can demonstrate by reasonable written evidence:

- 3.5.1 was, prior to the Commencement Date, in the possession of the Receiving Party and at its free disposal and was not obtained or otherwise acquired directly or indirectly from the Disclosing Party or its Affiliates or their respective employees, students or representatives; or
- 3.5.2 is subsequently disclosed to the Receiving Party without any obligations of confidence by a third party; or
- 3.5.3 is or becomes generally available to the public through no act or default of the Receiving Party or its agents, employees, Affiliates or Sub-licensees; or

- 3.5.4 the Receiving Party is required to disclose by or to the courts of any competent jurisdiction, or to any government regulatory agency or financial authority, provided that the Receiving Party shall:
  - (a) inform the Disclosing Party as soon as is reasonably practicable;
  - (b) at the Disclosing Party's request and cost seek to persuade the court, agency or authority to have the information treated in a confidential manner, where this is possible under the court, agency or authority's procedures; and
  - c) where the disclosure is unavoidable, limit the disclosure of Confidential information to the minimum extent required by law; or
- 3.5.5 which a Party is advised by its information officer that it is required to disclose under the Freedom of Information Act 2000 or the Environmental Information Regulations 2004.

### 3.6 Disclosure to Employees

The Receiving Party shall procure that all of its employees, contractors, Affiliates and Sub-licensees who have access to any of the Disclosing Party's Confidential Information to which Clause 3.3 applies, shall be made aware of the obligations of confidence and enter into written undertakings of confidentiality at least as restrictive as those set forth herein (which it undertakes to enforce and for which it is legally responsible) and the Receiving Party shall only disclose the Disclosing Party's Confidential Information to those of its subsidiaries, employees, and officers as need to have access thereto wholly necessarily and exclusively for the purposes of this Agreement.

### 4. CONSIDERATION

### 4.1 Initial Payment and Allocation of Shares

On or before the Commencement Date in consideration for the rights granted by UCLB under this Agreement:

- 4.1.1 the Licensee shall pay to UCLB £6,994 (six thousand nine hundred ninety-four pounds only) (exclusive of VAT) in terms of Patent Costs up to the Commencement Date, which payment shall be non-refundable and non-deductible; and
- 4.1.2 Meira shall
  - (a) allot and issue to UCLB such number of fully paid-up (and credited as fully paid-up) Consideration Shares ranking pan passu with the existing Convertible Preferred C Shares of £0.00001 each in the capital of Meira that have the equivalent cash value of £100,000, which the Parties agree is [\*\*\*] Consideration Shares;

- (b) deliver to UCLB a copy or extract of the resolutions adopted by the board of directors of Meira approving the allotment and issue of the Consideration Shares to UCLB; and
- (c) enter UCLB's name in Meira's register of members as the holder of the Consideration Shares and deliver to UCLB a duly executed share certificate in respect of the Consideration Shares.

# 4.2 Milestone Payments

Within [\*\*\*] ([\*\*\*]) days following achievement of each of the following milestone events by Licensee, its Affiliates or Sub-licensees, the Licensee shall notify UCLB in writing that the relevant milestone event has been achieved, provide documentary evidence of such achievement as appropriate and pay to UCLB, within a period of [\*\*\*] days, the amount(s) set out next to such milestone event below:

Milestone Event	Amount to be paid
[***]	£[***]
[***]	£[***]

### 4.3 Annual Management Fees

On each date referred to in the following table, the Licensee shall pay to UCLB the annual management fee set out next to such date in the table.

Date	Amount to be paid
Upon each anniversary of the Commencement Date until [***]	£50,000

### 4.4 Sales Linked Milestone Payments

Upon achievement of each of the sales linked milestones set out in the following table by the Licensee, its Affiliates or Sub-licensees, the Licensee shall notify UCLB in writing that the relevant sales linked milestone has been achieved, provide the relevant documentary evidence and pay to UCLB the amount(s) set out next to such event in the table:

Sales Linked Milestones	Amount to be paid
When Net Sales Value reaches £[***]	£[***]
On the next $\mathfrak{L}[***]$ of Net Sales Value (when sales cumulatively reach $\mathfrak{L}[***]$ )	£[***]
On the next $\mathfrak{L}[***]$ of Net Sales Value (When sales cumulatively reach $\mathfrak{L}[***]$ )	£[***]
On the next $\mathfrak{L}[***]$ of Net Sales Value (when sales cumulatively reach $\mathfrak{L}[***]$ )	£[***]
On the next $\mathfrak{L}[***]$ of Net Sales Value (when sales cumulatively reach $\mathfrak{L}[***]$ )	£[***]
On the next $\mathfrak{L}[***]$ of Net Sales Value (when sales cumulatively reach $\mathfrak{L}[***]$ )	£[***]

### 4.5 Royalties on Net Sales

For each Licensed Product in each country, the Licensee shall pay to UCLB a royalty of [\*\*\*]% ([\*\*\*] per cent) being a percentage of the Net Sales Value of all Licensed Products sold by Licensee, its Affiliates or Sub-licensees. The Licensee's obligations to pay such royalty for a given Licensed Product in a given country shall begin after the First Commercial Sale of such Licensed Product in such country and shall end on the later to occur of the following: (a) expiration of the last Valid Claim of a Patent claiming such Licensed Product in such country; or (b) the tenth (10th) anniversary of the date of such First Commercial Sale in such country; or (c) the expiration of any Regulatory Exclusivity with respect to all Licensed Products in the relevant country.

### 4.6 Combination Products

If any Licensed Products are incorporated in any other product ("Combination Product") sold by the Licensee or its Affiliates and the Licensed Product is not priced separately from the Combination Product, the Net Sales Value of such Licensed Product shall be deemed to be the fair market value of the Licensed Product in the country of sale when sold separately or if not sold separately in the country of sale, in comparable countries and territories or if neither of the foregoing apply, a reasonable amount which fairly reflects the value of the Licensed Product within the Combination Product assuming the Licensed Product is not being sold as a loss leader.

### 4.7 Payment Frequency

Royalties due under this Agreement, except for the payments due under Clauses 4.1.1, 4.2, 4.3 and 4.4, which are payable upon the date/time specified in Clauses 4.1.1, 4.2, 4.3, and 4.4 as appropriate, shall be paid within [\*\*\*] ([\*\*\*]) days following the end of each calendar quarter ending on 31 March, 30 June, 30 September and 31 December in each year, in respect of sales of Licensed Products made during such quarter, and within [\*\*\*] ([\*\*\*]) days following the termination of this Agreement.

### 4.8 Payment terms

All sums due under this Agreement:

- 4.8.1 are exclusive of Value Added Tax which where applicable will be paid by the Licensee to UCLB in addition;
- 4.8.2 shall be paid in pounds sterling in cash by transferring an amount in aggregate to the following Account name: UCL Business Plc, Sort Code: 20 10 53, Account number: 30782270, Address: Barclays Bank Plc, PO Box 11345, London, W12 8GG, and in the case of income or amounts received by the Licensee or its Affiliates in a currency other than pounds sterling, the royalty shall be calculated in the other currency and then converted into equivalent pounds sterling at the relevant daily spot rate for that currency as quoted in the Financial Times newspaper on the last business day of the quarter in relation to which the royalties are payable;
- 4.8.3 will be made without any set-off, deduction or withholding except as may be required by law. If the Licensee is required by law to make any deduction or to withhold any part of any amount due to UCLB under this Agreement, the Licensee will give to UCLB proper evidence of the amount deducted or withheld and payment of that amount to the relevant taxation authority, and will do all things in its power to enable or assist UCLB to claim exemption from or, if that is not possible, to obtain a credit for the amount deducted or withheld under any applicable double taxation or similar agreement from time to time in force; and
- 4.8.4 shall be made by the due date, failing which UCLB may charge interest on any outstanding amount on a daily basis at a rate equivalent to 3% above the Bank of England pound sterling base rate then in force in London.

### 4.9 Royalty Statements

The Licensee shall send to UCLB, at the same time as each royalty payment is made in accordance with Clause 4.5, a statement setting out for the relevant calendar quarter:

- 4.9.1 in respect of each territory or region in which Licensed Products are sold;
- 4.9.2 the types of Licensed Product sold;
- 4.9.3 the quantity of each type sold;
- 4.9.4 the total invoiced price for each type of Licensed Product sold;
- 4.9.5 where relevant, details of any Licensed Products that have been sold other than on arm's length terms for a cash consideration, including the relevant open market price or (if not available) the reasonable price attributed thereto;
- 4.9.6 the amounts deducted from the Net Sales Value as referred to in paragraph (i) to (iv) of that definition (broken down on a product by product and category by category basis); and
- 4.9.7 the aggregate royalties on Net Sales Value due to UCLB;

in each case expressed both in local currency and pounds sterling and showing the conversion rates used, during the period to which the royalty payment relates.

#### 4.10 Records

The Licensee shall keep at its normal place of business detailed and up to date records and accounts showing the quantity, description and invoiced price or non-cash consideration for all Licensed Products sold by it or its Affiliates or on its or its Affiliates' behalf, broken down in each case on a country by country basis, and being sufficient to ascertain the payments due to UCLB under this Agreement.

The Licensee shall make such records and accounts available, on reasonable notice, for inspection during business hours by an independent chartered accountant nominated by UCLB for the purpose of verifying the accuracy of any statement or report given by the Licensee to UCLB under this Clause 4.10. The Licensee shall co-operate reasonably with any such accountant, and shall promptly provide all information and assistance reasonably requested by such accountant. The accountant shall be required to keep confidential all information learnt during any such inspection, and to disclose to UCLB only such details as may be necessary to report on the accuracy of the Licensee's statement or report. UCLB shall be responsible for the accountant's charges unless the accountant certifies that there is an inaccuracy of more than [\*\*\*]% ([\*\*\*] percent) in any royalty statement, in which case the Licensee shall pay his charges in respect of that inspection.

The Licensee shall ensure that UCLB has the same rights as those set out in this Clause 4.10 in respect of the Licensee's Affiliates and Sub-licensees.

The Licensee shall co-operate with UCLB in good faith to resolve any discrepancies identified during any such inspection and shall pay any shortfall in the amounts paid to UCLB under this Agreement, together with interest on late payment as specified in Clause 4.8.4, within 30 days following receipt of a copy of the independent chartered accountant's report.

### 4.11 Accounting Standards

Where this Agreement requires a financial calculation to be made or an action to be taken, such calculation or action will be made or taken in accordance with the generally accepted accounting principles from time to time approved by the United Kingdom's Financial Reporting Council, or any successor body, applicable as at the date on which such calculation or action is made or taken.

### 5. COMMERCIALISATION

### 5.1 General Diligence

The Licensee shall use Diligent Efforts to develop and commercially exploit Licensed Products throughout the Territory (including obtaining all and any regulatory approvals which may be required to market and sell the Licensed Products) and to maximise sales for the benefit of both Parties.

### 5.2 Competing Activities

The Licensee shall notify UCLB in confidence if it or any of its Affiliates or its Sub-licensees commences any marketing, sale or commercialisation of any Competing Product or enters into an agreement with any other person with respect to any such activities.

### 5.3 Development Plan

The Licensee's initial plan for developing and commercialising Licensed Products is set out in Schedule 4 (the "Initial Development Plan"). The Licensee shall provide to UCLB on each anniversary of the Commencement Date a written update to the Initial Development Plan that shall:

- 5.3.1 report on all activities conducted under this Agreement by the Licensee and its Affiliates and Sub-licensees since the Commencement Date or the date of the previous update (as appropriate);
- 5.3.2 (where applicable) set out the milestone events achieved since the Commencement Date or the date of the previous update (as appropriate) and the Licensee's reasonable estimate of the dates for achieving any future milestone events;
- 5.3.3 set out the current and projected activities being taken or planned to be taken by the Licensee and its Affiliates and Sub-licensees to bring Licensed Products to market, and to maximise the sale of Licensed Products in the Territory; and
- 5.3.4 set out the Licensee's projected sales of Licensed Products (based on the Licensee's current forecasts) for each of the next [\*\*\*] ([\*\*\*]) years following the date of the report.

UCLB's receipt or approval of any update to the Updated Development Plan shall not be taken to waive or qualify the Licensee's obligations under Clause 5.1.

### 5.4 Annual Meeting

In respect of the Licensed Technology, the Licensee will on UCLB's request meet with UCLB at least once per calendar year, following the submission of the update to the relevant Development Plan pursuant to Clause 5.3, to discuss progress with development and commercialisation of the Licensed Technology and where relevant the Licensee's efforts to maximise sales of Licensed Products.

### 5.5 Reporting of First Commercial Sale

The Licensee will, for each Licensed Technology, promptly notify UCLB in writing of the First Commercial Sale of each Licensed Product on a commercial basis in each country within the Territory.

### 5.6 Reporting for Impact Purposes

- The Licensee acknowledges that part of UCLB's purpose in licensing the Patents, Know-how and the Materials to the Licensee pursuant this Agreement is to ensure that the Patents, Know-how and the Materials are made available for use and commercial exploitation with the intention of benefitting society and the economy. In order to enable UCLB and UCL to monitor the benefit that they are providing, and to enable UCL to demonstrate the impact of its research activities, to society and the economy, the Licensee will upon request provide to UCLB [\*\*\*], a written report describing in reasonable detail how it has used the Patents, Know-how and the Materials and the societal and economic benefits generated therefrom.
- UCLB shall notify and seek permission from the Licensee in advance, in writing if it wishes to use any written reports received from the Licensee (and the information contained therein) pursuant to Clause 5.6.1 in applications for research or other grant related funding and in submissions to Higher Education funding bodies such as HEFCE and/ or HEIF (or any replacements for either of those entities) and like entities, supplying a written copy of the application for research or other grant related funding or submission (or the relevant sections thereof). The Licensee will respond to UCLB in writing within [\*\*\*] ([\*\*\*]) days of receipt of such written information and subject to the removal of any confidential information as notified in such written request by the Licensee, UCLB and UCL shall be entitled to submit the approved applications for research or other grant related funding and in submissions to Higher Education funding bodies such as HEFCE and/ or HEIF (or any replacements for either of those entities) and like entities.

### 5.7 Quality

The Licensee shall ensure that all of the Licensed Products marketed by it and its Affiliates and Sub-licensees are of satisfactory quality and comply with all applicable laws and regulations in each part of the Territory.

### 5.8 Marking of Licensed Products

To the extent permitted under the laws of any country, the Licensee shall mark and cause its Affiliates and Sub-Licensees to mark each Licensed Product with the number of each issued Patent which applies to the Licensed Product and a statement that such Licensed Products are sold under licence from UCL Business plc.

### 5.9 Disposals of Licensed Products for Free

Notwithstanding the terms of Clause 5.1, the Licensee shall be entitled to supply a reasonable number of Licensed Products to third parties free of charge as promotional items for the purpose of establishing a market for the Licensed Products in the relevant country or territory or for research, evaluation and testing purposes, or for clinical development, provided that the quantity of Licensed Products supplied for free (or for the cost of manufacture) in each country or territory is not excessive and is in line with normal industry practice in such country or territory. Any Licensed Products disposed of to third parties in accordance with this Clause 5.9 shall not be taken into account for the purposes of calculating Net Sales Value.

### 5.10 Referral to Expert

If UCLB considers at any time during the period of this Agreement that the Licensee has failed to comply with its obligations under Clause 5.1 or 5.3, then the matter shall be referred to an independent expert to answer the following questions:

- 5.10.1 whether the Licensee has complied with its obligations under Clause 5.1 or 5.3; and if not
- 5.10.2 what specific action the Licensee should have taken and/or now needs to take ("Specific Action") in order to fulfil such obligations and within what period the Specific Action should be taken ("Action Period").

The independent expert shall be appointed in accordance with the provisions of Schedule 2 and his decision shall be final and binding on the Parties.

### 5.11 Consequences of Expert's Decision

If the expert determines that the Licensee has failed to comply with its obligations under Clause 5.1 or 5.3, and if the Licensee fails to take the Specific Action within the Action Period, UCLB shall be entitled, by giving, at any time within [\*\*\*] ([\*\*\*]) months after the end of that Action Period, not less than [\*\*\*] ([\*\*\*]) months' notice, to (a) convert the licence granted under Clause 2.1.1 into a non-exclusive licence or (b) terminate this Agreement.

### 6. ACCESS TO MEDICINES AND ETHICAL LICENSING

### 6.1 General Diligence

The Licensee agrees to use Diligent Efforts to develop and commercially exploit Licensed Products in a manner consistent with ethical and socially responsible licensing principles, including requiring all Sub-licensees and other parties involved in the development and commercial exploitation of Licensed Products to agree in writing to comply with ethical and socially responsible licensing principles.

### 6.2 Supply to Developing Countries

### 6.2.1 Supply by the Licensee

The Licensee shall use Diligent Efforts to supply the Licensed Products to customers in At-Cost Markets at a Cost-Based Price and to meet market demand for the Licensed Products in those markets.

### 6.2.2 Sub-Licensing in Developing Country markets

If the Licensee is unable to supply the Licensed Product at a Cost-Based Price in any At-Cost Market and to meet market demand for the Licensed Products in those markets, it shall use Diligent Efforts to license one or more Developing Country Manufacturers on Reasonable Developing Country License Terms to manufacture, distribute and sell the Licensed Product at a Cost-Based Price in that At-Cost Market.

### 6.3 Reporting

The Licensee shall keep UCLB regularly updated regarding the Licensee's efforts to supply the Licensed Products in accordance with the requirements outlined in Clauses 6.1 and 6.2.

### 6.4 Step In Rights

- 6.4.1 If at any time UCLB acting reasonably considers that the Licensee is not meeting its obligations under Clauses 6.1 and 6.2 in relation to the supply of the Licensed Products to customers in At-Cost Markets, UCLB may be written notice require the Licensee to seek one or more third parties to develop, commercialise and supply the Licensed Products to customers in At-Cost Markets.
- 6.4.2 If the Licensee following a written requirement from UCLB refuses to grant a sublicense to or is unable to identify a third party to develop, commercialise and supply the Licensed Products to customers in At-Cost Markets, then UCLB notwithstanding the rights granted to the Licensee under this Agreement shall have the right to seek a third party and/ or to grant to a third party a license to manufacture, have manufactured, use, sell, offer for sale and import the Licensed Products for supply in the At-Cost market on Reasonable Developing Country License Terms.

### 7. COMPLIANCE WITH LAWS

### 7.1 General Compliance with Laws

The Licensee will at all times (and will ensure its Affiliates and Sub-licensees) comply with all legislation, rules, regulations and statutory requirements applying to and obtain any consents necessary for its use of the Patents, the Know-how and the Materials, the development, manufacture, and sale of Licensed Products in any country or territory.

### 7.2 Bribery Act

The Licensee shall (and shall procure that any persons associated with it engaged in the performance of this Agreement including its Affiliates and Sub-licensees shall):

- 7.2.1 comply with all applicable laws and codes of practice relating to anti-bribery and anti-corruption including the Bribery Act 2010 and without prejudice to the foregoing generality, shall not engage in any activity, practice or conduct which would constitute an offence under sections 1, 2 or 6 of the Bribery Act 2010 or do or omit to do any act that will cause or lead UCLB to be in breach of the Bribery Act 2010;
- 7.2.2 comply with UCLB's ethics, anti-bribery and anti-corruption policies as notified to the Licensee from time to time and have, maintain in place and enforce throughout the term of this Agreement adequate procedures to ensure compliance with Clause 7.2.1; and
- 7.2.3 promptly report to UCLB any request or demand for any undue financial or other advantage of any kind received in connection with the performance of this Agreement.

For the purpose of this Clause 7.2, the meaning of adequate procedures and whether a person is associated with another person shall be determined in accordance with the Bribery Act 2010 (and any guidance issued under section 9 of that Act). Breach of this Clause 7.2 shall be deemed a material breach of this Agreement entitling UCLB to terminate under Clause 10.2.1.

### 7.3 Export Control Regulations

The Licensee shall ensure that, in using the Patents, Know-how or Materials and in selling Licensed Products, it and its Affiliates, employees, sub-contractors and Sub-licensees comply fully with any EU or UK legislation or regulation, from time to time in force, which impose arms embargoes or control the export of goods, technology or software, including weapons of mass destruction and arms, military, paramilitary and security equipment and dual-use items (items designed for civil use but which can be used for military purposes) and certain drugs and chemicals.

### 8. INTELLECTUAL PROPERTY

#### 8.1 Obtain and Maintain the Patents

- 8.1.1 The Licensee shall be responsible for the drafting, filing, prosecution and maintenance of all of the Patents at the Licensee's cost and expense. Subject to resource availability, UCLB shall use commercially reasonable efforts to provide such assistance as the Licensee may request to prosecute and maintain the Patents[\*\*\*] that may be incurred in providing such assistance.
- 8.1.2 The Patents will be filed, prosecuted and maintained in the countries and territories where Licensee normally files its patent applications and patents for other gene therapy products. The Licensee shall notify UCLB of any decisions as to which (if any) additional countries to file and maintain Patents in.
- 8.1.3 The Licensee shall consult with UCLB in relation to all material changes to the patent claims or specifications that would have the effect of reducing or limiting the scope of the Patents, and not make any such changes without the prior written consent of UCLB. Such consent shall not be unreasonably withheld or delayed provided that UCLB has been given as much notice as is practicable, and in any event no less than [\*\*\*] days' notice (or such shorter period for response dictated by the relevant patent office) of such proposed changes, and has been given an opportunity to file divisionals, continuations and/or such other types of protection to cover any claims or subject matter that the Licensee intends to remove from the scope of the Patents. If UCLB fails to respond before the end of the [\*\*\*] day period (or such shorter period for response dictated by the relevant patent office), the Licensee may proceed with the proposed changes to the patent claims or specifications. The Licensee will ensure that UCLB receives copies of all correspondence to and from Patent Offices in respect of the Patents, including copies of all documents generated in or with such correspondence, and shall be given reasonable notice (or such shorter period for response dictated by the relevant patent office) of and the opportunity to participate in any conference calls or meetings with the Licensee's patent attorneys in relation to the drafting, filing, prosecution and maintenance of the Patents, so that UCLB may be continuously informed of progress with the drafting, filing, prosecution and maintenance of the Patents. Such involvement of UCLB under this Clause 8.1.3 shall be at UCLB's cost and expense.
- 8.1.4 If the Licensee wishes to abandon any application contained with the Patents or not to maintain any such Patent, it shall give [\*\*\*] ([\*\*\*]) months' prior written notice to UCLB and on the expiry of such notice period the licences of the relevant Patents granted to the Licensee under this Agreement shall cease.

8.1.5 In the event that any of rights granted hereunder become non-exclusive, responsibility for the drafting, filing, prosecution and maintenance of all of the Patents shall revert to UCLB.

### 8.2 Infringement of the Patents, the Know-how and/or the Materials

- 8.2.1 The Licensee and UCLB shall promptly give to each other written notice if it becomes aware of any infringement or potential infringement of any of the Patents or any unauthorised use of the Know-how or the Materials or any challenge to the validity or ownership of the Patents, the Know-how or the Materials and the Licensee and UCLB shall consult with each other to decide the best way to respond to such infringement, unauthorised use or challenge.
- 8.2.2 The Licensee shall have the primary obligation and right to take action against any third party alleged to be infringing the Patents or making unauthorised use of the Know-how or the Materials and to defend the Patents against challenges to validity or ownership at its sole expense, provided that:
  - (a) the Licensee and UCLB shall use their commercially reasonable efforts to eliminate the infringement without litigation. If the efforts of the Licensee, and UCLB are not successful in eliminating the infringement within [\*\*\*] ([\*\*\*]) days after the infringer has been formally notified of the infringement by the Licensee, the Licensee shall have the right after consulting with UCLB, to commence suit on its own account;
  - (b) UCLB shall on the Licensee's request cooperate with the Licensee in such action [\*\*\*]; and
  - (c) the Licensee shall be solely responsible for the conduct of the action or for settlement thereof and shall be entitled to all damages received from such action, subject to Clause 8.2.4.
- 8.2.3 Before starting or defending or settling any legal action under Clause 8.2.2, the Licensee shall consult with UCLB as to the advisability of the action or defence or settlement, its effect on the good name of UCLB, the public interest, and how the action or defence should be conducted.
- 8.2.4 The Licensee shall [\*\*\*].
- 8.2.5 UCLB shall if reasonably requested by the Licensee agree to be joined in any suit to enforce such rights or will take such action in its own name [\*\*\*] and shall have the right to be separately represented by its own counsel [\*\*\*]. Notwithstanding the foregoing, [\*\*\*].

### 8.3 Infringement of Third Party Rights

- 8.3.1 If any warning letter or other notice of infringement is received by the Licensee or UCLB, or legal suit or other action is brought against the Licensee or UCLB, alleging infringement of third party rights in the manufacture, use or sale of any Licensed Product or use of any Patents, Know-how or Materials, that Party shall (in the case of UCLB) promptly provide full details to the Licensee and (in the case of the Licensee) promptly provide full details to UCLB, and the Licensee and UCLB shall discuss the best way to respond.
- 8.3.2 The Licensee shall have the right but not the obligation to defend such suit to the extent it relates to Licensee's or its Affiliates' or Sub-licensee's activities and shall have the right to settle with such third party, provided that [\*\*\*]. In the event that the Licensee, Affiliates or Sub-licensees do not take forward an action, UCLB shall have the right, at its sole discretion, to defend such suit under its sole control and [\*\*\*].

### 9. WARRANTIES AND LIABILITY

### 9.1 Warranties by UCLB

UCLB warrants and undertakes as follows to its reasonable knowledge and without having undertaken any due and careful enquires whether specific or general in nature:

- 9.1.1 It is the owner of the Patents;
- 9.1.2 it has the authority to grant the licences under this Agreement; and.
- 9.1.3 so far as it is aware (having made no enquiry of any third parties or conducted any freedom to operate searches), use and exploitation of the Patents will not infringe the intellectual property rights of any third party.

UCLB warrants and undertakes:

- 9.1.4 <u>it has full power and authority to enter into and perform this Agreement which, when executed, will constitute valid and legally binding obligations on UCLB; and</u>
- 9.1.5 entry into this Agreement and subscription for the Consideration Shares will not result in any breach of, or violation of the terms or provisions of, the constitutional documents of UCLB or any other agreement or instrument by which it is bound.

### 9.2 Warranties by the Licensee

The Licensee warrants and undertakes that:

- 9.2.1 <u>full power and authority to enter into and perform this Agreement, which, when executed, will constitute valid and legally binding obligations on the Licensee;</u>
- 9.2.2 <u>entry into this Agreement will not result in any breach of, or violation of the terms or provisions of, the constitutional documents of the Licensee or any other agreement or instrument by which it is bound;</u>
- 9.2.3 so far as it is aware (having made no enquiry of any third parties), use and exploitation of the Patents will not infringe the intellectual property rights of any third party;
- 9.2.4 neither it nor any of its Affiliates is currently researching, developing, marketing, selling or otherwise commercialising any Competing Product ("Competing Activities"), nor has any of them entered into an agreement with any other person with respect to any Competing Activities; and
- 9.2.5 it shall notify UCLB if it or any of its Affiliates or its Sub-licensees commences any Competing Activities or enters into an agreement with any other person with respect to any Competing Activities.

### 9.3 Warranties by Meira

Meira warrants and undertakes that:

- 9.3.1 <u>full power and authority to enter into and perform this Agreement which, when executed, will constitute valid and legally binding obligations on Meira;</u>
- 9.3.2 <u>entry into this Agreement and the issue and allotment of the Consideration Shares will not result in any breach of, or violation of the terms or provisions of, the constitutional document of Meira or any other agreement or instrument by which it is bound:</u>
- 9.3.3 it has all necessary authority and approvals to allot and issue the Consideration Shares (including a resolution passed by its shareholders giving its directors authority to allot pursuant to section 551 of the Companies Act 2006); and
- 9.3.4 any and all pre-emption rights have been disapplied or waived by all relevant shareholders in relation to the allotment and issue of the Consideration Shares; and
- 9.3.5 The Consideration Shares, when issued in accordance with this Agreement, will be validly allotted and issued, fully paid and free of liens, charges, encumbrances and other third party rights.

### 9.4 Acknowledgements

The Licensee acknowledges that:

- 9.4.1 the inventions claimed in the Patents, and the Know-how and the Materials are at an early stage of development. Accordingly, specific results cannot be guaranteed and any results, materials, information or other items (together "Delivered Items") provided under this Agreement are provided "as is" and without any express or implied warranties, representations or undertakings. As examples, but without limiting the foregoing, UCLB does not give any warranty that Delivered Items are of merchantable or satisfactory quality, are fit for any particular purpose, comply with any sample or description, or are viable, uncontaminated, safe or non-toxic.
- 9.4.2 UCLB has not performed any searches or investigations into the existence of any third party rights that may affect any of the Patents, Know-how or Materials or the use and exploitation of any of the Patents, Know-how or Materials.

### 9.5 No Other Warranties

- 9.5.1 Each of the Parties acknowledges that, in entering into this Agreement, it does not do so in reliance on any representation, warranty or other provision except as expressly provided in this Agreement, and any conditions, warranties or other terms implied by statute or common law are excluded from this Agreement to the fullest extent permitted by law.
- 9.5.2 Without limiting the scope of Clause 9.5.1, UCLB does not make any representation nor give any warranty or undertaking:
  - (a) express or implied, including, without limitation, any implied warranties of merchantability or of fitness for a particular purpose with respect to any Patent, trademark, software, non-public or other information, or tangible research property, licensed or otherwise provided to the Licensee hereunder and hereby disclaims the same;
  - (b) as to the efficacy or usefulness of the Patents, Know-how or Materials; or
  - (c) whatsoever with regard to the scope of any of the Patents or that any of the Patents is or will be valid or (in the case of an application) will proceed to grantor that such Patents may be exploited by the Licensee, Affiliate or Sub-licensee without infringing other patents; or
  - (d) that the use of any of the Patents, Know-how or Materials, Licensed Technology, the manufacture, sale or use of the Licensed Products, or the exercise of any of the rights granted under this Agreement will not infringe any intellectual property or other rights of any other person; or
  - (e) that the Know-how or any other information communicated by UCLB to the Licensee under or in connection with this Agreement will produce Licensed Products of satisfactory quality or fit for the purpose for which the Licensee intended or that any product will not have any defect, latent or otherwise, and whether or not discoverable by inspection; or

- (f) as imposing any obligation on UCLB to bring or prosecute actions or proceedings against third parties for infringement or to defend any action or proceedings for revocation of any of the Patents; or
- (g) as imposing any liability on UCLB in the event that any third party supplies Licensed Products to customers located in the Territory; or
- (h) that there will be no similar or competitive products or services manufactured, used, sold or supplied by any third party in the Territory.

### 9.6 Responsibility for Development of Licensed Products

The Licensee shall be exclusively responsible for its and its Affiliates' and Sub-licensees' use of the Patents, Know-how and Materials, the technical and commercial development and manufacture of Licensed Products and for incorporating any modifications or developments thereto that may be necessary or desirable, for all Licensed Products sold or supplied, notwithstanding any consultancy services or other contributions that UCLB and/or UCL may provide in connection with such activities.

### 9.7 Indemnity

The Licensee shall indemnify each of UCLB and UCL, and each of their respective officers, directors, Council members, employees and representatives (together, the "Indemnitees") against all third party Claims that may be asserted against or suffered by any of the Indemnitees and which relate to:

- 9.7.1 the use by the Licensee or any of its Affiliates or Sub-licensees of any of the Patents, Know-how or Materials; or
- 9.7.2 the development, manufacture, use, marketing or sale of, or any other dealing in, any of the Licensed Products, by or on behalf of the Licensee or any of its Affiliates or Sub-licensees, or subsequently by any customer or any other person, including claims based on product liability laws.

The indemnity given by the Licensee to each Indemnitee under this Clause 9.7 will not apply to any third party Claim to the extent that it is attributable to the negligence, gross negligence, reckless misconduct or intentional misconduct of any Indemnitee.

### 9.8 Limitations of Liability

- 9.8.1 To the extent that UCLB or any of its Affiliates has any liability in contract, tort, or otherwise under or in connection with this Agreement, including any liability for breach of warranty, their liability shall be limited in accordance with the following provisions of this Clause 9.8.
- 9.8.2 The aggregate liability of UCLB and any of its Affiliates shall be limited to the total income that UCLB has received from the Licensee pursuant to this Agreement (but excluding any other costs or expenses associated with drafting, filing, prosecuting, maintaining or defending any Patents or providing any assistance to the Licensee) during the period of [\*\*\*] ([\*\*\*]) years preceding the date on which the liability arises, or fifty thousand pounds (£50,000) sterling, whichever is the higher.
- 9.8.3 The liability of the Licensee to UCLB shall be limited to the limit of its insurance as set out in Clause 9.9.1, except that in the case of product liability, the liability of the Licensee under this Agreement shall be unlimited.
- 9.8.4 In no circumstances shall any Party or any Indemnitee be liable for any loss, damage, costs or expenses of any nature that is (a) of an indirect, special or consequential nature or (b) any loss of profits (whether direct or indirect), revenue, business opportunity or goodwill, which arises directly or indirectly from that Party's breach or non performance of this Agreement, or negligence in the performance of this Agreement or from any liability arising in any other way out of the subject matter of this Agreement even if the Party bringing the claim has advised any other Party or the relevant Indemnitee of the possibility of those losses arising, or if such losses were within the contemplation of the Parties or the Indemnitee.
- 9.8.5 Nothing in this Agreement excludes any Party's liability to the extent that it may not be so excluded under applicable law, including any such liability for death or personal injury caused by that Party's negligence, or liability for fraud or fraudulent misrepresentation.

### 9.9 Insurance

9.9.1 The Licensee shall take out with a reputable insurance company and maintain at all times during the term of this Agreement public and product liability and professional indemnity insurance including against all loss of and damage to property (whether real, personal or intellectual) and injury to persons including death arising out of or in connection with this Agreement and the Licensee's and its Affiliates' and Sub-licensees' use of the Patents, Know-how or Materials and use, sale of or any other dealing in any of the Licensed Products. Such insurances may be limited in respect of one claim provided that such limit must be at least [\*\*\*] pounds (£[\*\*\*]) sterling, unless the Licensee commences any business in manufacturing, distribution, supply or otherwise make available to the public any products, in which case such limit must be at least [\*\*\*] pounds (£[\*\*\*]) sterling. Such insurance shall continue to be maintained for a further [\*\*\*] years from the end of this Agreement.

9.9.2 The Licensee will produce to UCLB at all times upon demand proof that the insurance cover required pursuant to Clause 9.9.1 is in force and evidence that all premiums have been paid up to date. If UCLB becomes aware that the Licensee has failed to maintain the insurance required pursuant to Clause 9.9.1, UCLB may effect such insurance and the Licensee will reimburse UCLB for the reasonable cost of effecting and maintaining such insurance on demand.

### 10. DURATION AND TERMINATION

### 10.1 Commencement and Expiry

This Agreement and the licences granted hereunder, shall come into effect on the Commencement Date and, unless terminated earlier in accordance with this Clause 10, the licences granted hereunder shall continue in force on a country by country basis until the later of the last payment obligation of Licensee expires under this Agreement. Upon such expiry, Licensee's licenses under this Agreement shall become full-paid, perpetual and irrevocable.

### 10.2 Early Termination

Each Party (the "Terminating Party") may terminate this Agreement at any time by notice in writing to the other Parties ("Other Parties"), such notice to take effect as specified in the notice:

- 10.2.1 If, in the case of UCLB, either of the Other Parties, or in the case of the Licensee or Meira, UCLB, is in material breach of this Agreement and, in the case of a breach capable of remedy within thirty (30) days, the breach is not remedied within thirty (30) days of the Other Parties receiving notice specifying the breach and requiring its remedy; or
- 10.2.2 if:
  - (a) in the case of UCLB, either of the Other Parties, or in the case of the Licensee or Meira, UCLB, becomes insolvent or unable to pay its debts as and when they become due;
  - (b) an order is made or a resolution is passed for the winding up of in the case of UCLB, either of the Other Parties, or in the case of the Licensee or Meira, UCLB (other than voluntarily for the purpose of solvent amalgamation or reconstruction);
  - (c) a liquidator, administrator, administrative receiver, receiver or trustee is appointed in respect of the whole or any part of, in the case of UCLB, either of the Other Parties', or in the case of the Licensee or Meira, UCLB's, assets or business;

- (d) in the case of UCLB, either of the Other Parties, or in the case of the Licensee or Meira, UCLB, makes any composition with its creditors:
- (e) in the case of UCLB, either of the Other Parties, or in the case of the Licensee or Meira, UCLB, ceases to continue its business; or
- (f) any event analogous to the events referred to in paragraphs (a) to (e) above occurs in any other jurisdiction.
- 10.3 UCLB may terminate this Agreement by giving written notice to the Licensee and Meira, such termination to take effect forthwith or as otherwise stated in the notice:
  - 10.3.1 if there is any change of Control of the Licensee involving the categories of persons or Affiliates of persons prohibited by Clause 2.3;
  - 10.3.2 if Meira fails to comply with its obligations under Clause 4.1.2; or
  - the Licensee is in persistent breach of the Agreement and where the Licensee and UCLB have failed to agree a mechanism to remedy the persistent nature of such breaches within a reasonable period following UCLB notifying the Licensee of the persistent breach and requesting that the Licensee enters into discussions with UCLB as to mechanisms for remedying the persistent breaches or if the Licensee and UCLB have agreed a mechanism to remedy the persistent breach but that mechanism if not fully complied with by the Licensee; or
  - 10.3.4 if the Licensee shall enter into any sub-licence with any of the categories of persons or Affiliates of persons prohibited by Clause 2.3 which may, adversely affect UCL's and/or UCLB's reputation.
- 10.4 A Party's right of termination under this Agreement, and the exercise of any such right, shall be without prejudice to any other right or remedy (including any right to claim damages) that such Party may have in the event of a breach of contract or other default by any other Party.

### 10.5 Consequences of Termination

10.5.1 Upon expiry of the period of this Agreement, and subject to all royalties and any other sums due to UCLB under this Agreement having been duly paid, the Licensee shall have a fully paid up licence to the Patents, the Know-how and the Materials of the same scope as set forth in Clauses 2.1.1 and 2.1.2 without any further obligation to pay any further sums to UCLB under Clause 4. Notwithstanding the foregoing the Licensee acknowledges that once each Patent expires or is abandoned or withdrawn or allowed to lapse in any country or territory, third parties in that country or territory will be entitled to use the inventions claimed in the Patent and that accordingly the licence granted to the Licensee under Clause 2.1.1 will no longer be exclusive in that country or territory.

- 10.5.2 Upon termination of this Agreement by UCLB under Clause 10.2.1 (for Licensee's uncured material breach) or under Clause 10.3:
  - (a) the Licensee and its Affiliates and Sub-licensees shall be entitled to sell, use or otherwise dispose of (subject to payment of royalties under Clause 4) any unsold or unused stocks of the Licensed Products for a period of six (6) months following the date of termination;
  - (b) subject to paragraph (a) above, any license that has not become fully paid-up in accordance with Clause 10.1 shall terminate and the Licensee and its Affiliates (and subject to Clause 2.3, its Sub-licensees) shall no longer be licensed to use or otherwise exploit the Patents and/or the Know-how and/or the Materials, in so far and for as long as any of the Patents remains in force and the Know-how remains confidential;
  - (c) the Licensee shall consent to the cancellation of any formal licence granted to it, or of any registration of it in any register, in relation to any of the Patents;
  - (d) the Licensee will, promptly on UCLB's request, provide (and will ensure that its patent agents provide) to UCLB all information, documentation and assistance (including executing documents) which UCLB may reasonably require to enable it to continue with the drafting, filing, prosecution and maintenance of the Patents;
  - (e) except as set out in Clause 2.3, all sub-licences of the Patents and/or the Know-how and/or the Materials granted by the Licensee pursuant to this Agreement will automatically terminate;
  - (f) UCLB shall, upon the written request of either of the other Parties, and each of the Licensee and Meira shall, upon the written request of UCLB, return or destroy any documents or other materials that are in its or its Affiliates possession or under its or their control and that contain the requesting Party's Confidential Information.
- 10.6 If Licensee may terminate this Agreement under Clause 10.2.1 (for UCLB or its Affiliates uncured material breach), then Licensee may elect, in lieu of terminating the entire Agreement, to have all licenses granted under this Agreement survive, subject to Licensee's fulfilment of [\*\*\*] percent ([\*\*\*]%) of its payment obligations under Clause 4 after what would have been the effective date of such termination.

10.7 Upon termination of this Agreement for any reason, the provisions of Clauses 1, 2.3, 2.5, 3.2 to 3.6, 4 (in respect of amounts paid and payable to UCLB in respect of the period up to and including the date of termination) 5.6, 7, 9, 10.5, 10.6, 10.7 and 11 of this Agreement shall remain in force.

### 11. GENERAL

### 11.1 Force Majeure

- 11.1.1 Any delays in or failure of performance by a Party under this Agreement will not be considered a breach of this Agreement and if and to the extent that such delay or failure is caused by occurrences beyond the reasonable control of that Party including acts of God; acts, regulations and laws of any government; strikes or other concerted acts of workers; fire; floods; explosions; riots; wars; rebellion; and sabotage; and any time for performance hereunder will be extended by the actual time of delay caused by any such occurrence.
- 11.1.2 If (a) UCLB or (b) the Licensee or Meira is prevented from carrying out its obligations:
  - (a) under this Agreement for a continuous period of [\*\*\*] ([\*\*\*]) months, the Licensee (in the case of (a) or UCLB (in the case of (b), may terminate this Agreement on giving [\*\*\*] ([\*\*\*]) days prior written notice provided always that at the date upon which termination becomes effective the Party which was prevented from carrying out its obligations under this Agreement remains so prevented.

### 11.2 Amendment

This Agreement may only be amended in writing signed by duly authorised representatives of the Parties.

### 11.3 Assignment and Third Party Rights

- 11.3.1 Subject to Clause 11.3.3, the Licensee shall not assign, mortgage, charge or otherwise transfer any rights or obligations under this Agreement, nor any of the Patents, Know-how or Materials, without the prior written consent of UCLB.
- 11.3.2 UCLB may assign all its rights and obligations under this Agreement together with its rights in the Patents, Know-how and Materials to any third party.
- 11.3.3 The Licensee, subject to obtaining the consent of UCLB which shall not be unreasonably withheld or delayed (except in relation to those categories of persons or Affiliates of persons prohibited by Clause 2.3), may assign all its rights and obligations under this Agreement together with its rights in the Patents, Know-how and Materials to any third party to which it transfers all or substantially all of its assets or business, provided that the assignee undertakes to UCLB to be bound by and perform the obligations of the assignor under this Agreement. However, the Licensee shall not have such a right to assign this Agreement if it is insolvent.

11.3.4 Meira shall not assign, mortgage, charge or otherwise transfer any rights or obligations under this Agreement without the prior written consent of UCLB.

### 11.4 Waiver

Any waiver given under or in relation to this Agreement shall be in writing and signed by or on behalf of the relevant Party. No failure or delay on the part of a Party to exercise any right or remedy under this Agreement shall be construed or operate as a waiver thereof, nor shall any single or partial exercise of any right or remedy preclude the further exercise of such right or remedy.

### 11.5 Invalid Clauses

If any provision or part of this Agreement is held to be invalid, amendments to this Agreement may be made by the addition or deletion of wording as appropriate to remove the invalid part or provision but otherwise retain the provision and the other provisions of this Agreement to the maximum extent permissible under applicable law.

### 11.6 No Agency

No Party shall act or describe itself as the agent of the other, nor shall it make or represent that it has authority to make any commitments on the other's behalf.

### 11.7 Interpretation

In this Agreement:

- the headings are used for convenience only and shall not affect its interpretation; references to persons shall include incorporated and unincorporated persons; references to the singular include the plural and vice versa; and references to the masculine include the feminine;
- 11.7.2 references to Clauses and Schedules mean clauses of, and schedules to, this Agreement;
- 11.7.3 references in this Agreement to termination shall include termination by expiry;
- 11.7.4 where the word "including" is used it shall be understood as meaning "including without limitation";
- any reference to any English law term for any action, remedy, method or judicial proceeding, legal document, legal status, court, official or any legal concept or thing shall in respect of any jurisdiction other than England be deemed to include what most nearly approximates in that jurisdiction to the English law term;

- 11.7.6 where there is any conflict or inconsistency between the main body of this Agreement and any of the schedules, then the main body of the Agreement shall prevail;
- 11.7.7 time shall be of the essence in relation to the performance of Meira's and the Licensee's obligations under this Agreement; and
- any reference to the sale of a Licensed Product by the Licensee or its Affiliates or Sub-licensees will be taken to include any supply or other disposal of Licensed Products, and the term sold shall be construed accordingly.

#### 11.8 Notices. Addresses for Service

- 11.8.1 Any notice to be given under this Agreement shall be in English, in writing and shall be delivered by first class recorded delivery mail (if sent to an inland address) or by international courier (if sent to an address outside of the United Kingdom), to the address of the relevant Party set out at the head of this Agreement, or such other address as that Party may from time to time notify to the other Parties in accordance with this Clause 11.8.
- 11.8.2 Notices sent as above shall be deemed to have been received [\*\*\*] ([\*\*\*]) working day after the day of posting in the case of delivery inland first class recorded delivery mail, or [\*\*\*] ([\*\*\*]) working days after the date of collection by the international courier.

### 11.9 Law and Jurisdiction

The validity, construction and performance of this Agreement, and any contractual and non-contractual claims arising hereunder, shall be governed by English law and shall be subject to the exclusive jurisdiction of the English courts to which the Parties hereby submit, except that a Party may seek an interim injunction (or an equivalent remedy) in any court of competent jurisdiction.

# 11.10 Entire Agreement

This Agreement, including its Schedules, sets out the entire agreement between the Parties relating to its subject matter and supersedes all prior oral or written agreements, arrangements or understandings between them relating to such subject matter (including Licence Addendum Number 2 entered into by UCLB and Licensee pursuant to a Licence Agreement dated 4 February 2015 ("Licence Agreement"), which, to the extent of subject matter of this Agreement, stands modified by this Agreement), and Licensee will not owe UCLB any payments for Licensed Products under such prior agreements. For clarity, the said Addendum Number 2 shall be deemed to be terminated and, as such, excluded from the scope of the Licence Agreement as of the Commencement Date. Subject to Clause 9.8.5, the Parties acknowledge that they are not relying on any representation, agreement, term or condition which is not set out in this Agreement.

### 11.11 Third Parties

Except for the rights of UCL as provided in Clause 2.4, the rights of the Indemnitees as provided in Clause 9.7, the limitations of liability afforded to the Indemnitees pursuant to Clause 9.8, who may in their own right enforce and rely on the provisions of those Clauses, this Agreement does not create any right enforceable by any person who is not a party to it ("Third Party") under the Contracts (Rights of Third Parties) Act 1999, but this Clause 11.11 does not affect any right or remedy of a Third Party which exists or is available apart from that Act.

### 11.12 Non-use of Names; Announcements

- 11.12.1 The Licensee shall not use, and shall ensure that its Affiliates and Sub-licensees do not use, the name, any adaptation of the name, any logo, trademark or other device of UCLB, nor of the inventors named on the Patents nor the Principal Investigators in any advertising, promotional or sales materials without prior written consent obtained from UCLB in each case, except that the Licensee may state that it is licensed by UCLB under the Patents.
- 11.12.2 Except as permitted under Clauses 3.4.1 and 5.6, no Party shall make any press or other public announcement concerning any aspect of this Agreement, or make any use of the name or trademarks of any other Party in connection with or in consequence of this Agreement, without the prior written consent of the relevant other Party.

#### 11.13 Escalation

If the Licensee or Meira on the one hand, and UCLB on the other, are unable to reach agreement on any issue concerning this Agreement or the Project within [\*\*\*] days after one either has notified the other of that issue, they will refer the matter to the [\*\*\*] in the case of UCLB, and to the [\*\*\*] in the case of the Licensee and Meira in an attempt to resolve the issue within the time specified elsewhere in this Agreement in the case of other disputes. Any Party may bring proceedings in a court of competent jurisdiction if the matter has not been resolved within that prescribed period, and any Party may apply to the court for an injunction, whether or not any issue has been escalated under this Clause 11.13.

<b>EXECUTED</b> on the date set out at the head of this Agreement	ıt.	
For and on behalf of	For and on behalf of	
UCL Business PLC	MEIRAGTX UK II LIMITED	
/s/ Anne Lane	/s/ Richard Giroux	
Signed	Signed	
Dr. Anne Lane	Rich Giroux	
Print name	Print name	
Executive Director UCL Business PLC	Director	
Title	Title	
14 March 2018	3.14.18	
Date	Date	
For and on behalf of		
MEIRAGTX LIMITED		
/s/ Alexandria Forbes		
Signed		
Alexandria Forbes		
Print name		
President & CEO		
Title		

Confidential Portions of this Exhibit marked as [\*\*\*] have been omitted pursuant to a request for confidential treatment and have been filed separately with the Securities and Exchange Commission.

Date

# **SCHEDULE 1**

# LICENSED TECHNOLOGY

Part A: The Patents

[\*\*\*]

Part B: The Know-how

a. [\*\*\*]

The Know-how Data:

1. [\*\*\*]

Part C: The Materials

1. [\*\*\*]

### **SCHEDULE 2**

### APPOINTMENT OF EXPERT

For the purposes of this Schedule 2 only, the "Parties" shall mean the Licensee and UCLB. If either Party wishes to appoint an independent expert (the "Expert") to determine any matter pursuant to any Clause of this Agreement, the following procedures will apply:

- 1. The Party wishing to appoint the Expert ("the Appointing Party") will serve a written notice on the other Party ("the Responding Party"). The written notice will specify the Clause pursuant to which the appointment is to be made and will contain reasonable details of the matter(s) which the Appointing Party wishes to refer to the Expert for determination
- 2. The Parties shall within [\*\*\*] ([\*\*\*]) days following the date of the Appointing Party's written notice use all reasonable efforts to agree who is to be appointed as the Expert to determine the relevant matter(s). If the Parties are unable to agree upon the identity of the Expert within that timescale, the Expert shall be appointed by the President (for the time being) of the Licensing Executives Society Britain and Ireland upon written request of either Party.
- 3. Each Party will within [\*\*\*] ([\*\*\*]) days following appointment of the Expert, prepare and submit to the Expert and the other Party a detailed written statement setting out its position on the matter(s) in question and including any proposals which it may wish to make for settlement or resolution of the relevant matter.
- 4. Each Party will have [\*\*\*] ([\*\*\*]) days following receipt of the other Party's written statement to respond in writing thereto. Any such response will be submitted to the other Party and the Expert.
- 5. The Expert will if he/ she deems appropriate be entitled to seek clarification from the Parties as to any of the statements or proposals made by either Party in their written statement or responses. Each Party will on request make available all information in its possession and shall give such assistance to the Expert as may be reasonably necessary to permit the Expert to make his/ her determination.
- 6. The Expert will issue his/ her decision on the matter(s) referred to him/ her in writing as soon as reasonably possible, but at latest within [\*\*\*] ([\*\*\*]) months following the date of his/ her appointment. The Expert's decision shall (except in the case of manifest error) be final and binding on the Parties.
- 7. The Expert will at all times act as an independent and impartial expert and not as an arbitrator.
- 8. The Expert's charges will be borne as he/ she determines in his written decision.

### **SCHEDULE 3**

### **DEFINITION OF TOBACCO INDUSTRY FUNDING (REVISED 2009)**

FROM THE CANCER RESEARCH UK CODE OF PRACTICE ON TOBACCO INDUSTRY FUNDING TO UNIVERSITIES.

http://www.cancerresearchuk.org/science/funding/terms-conditions/funding-policies/policy-tobacco/

A tobacco company is defined for the purposes of this policy as one that:

- Derives over 5% of revenues from manufacturing tobacco products;
- · Derives 15%+ of revenues from the manufacture of products necessary for the production of tobacco products;
- Derives 15% of revenues from the sale of tobacco products (and has 30 or more staff);
- Owns a tobacco company (the company owns 50% or more of a tobacco company);
- Is more than 50% owned by a company with tobacco involvement.

The following do not constitute tobacco industry funding for the purposes of this Code:

- legacies from tobacco industry investments (provided these are sold on immediately)
- funding from a trust or foundation no longer having any connection with the tobacco industry even though it may bear a name that (for historical reasons) has tobacco industry associations.

# SCHEUDLE 4

# INITIAL DEVELOPMENT PLAN

The Initial Development Plan for the Licensed Technology is shown below

<u>Activity</u>	Timeline
Phase I/II Start	[***]
Phase I/II Finish	[***]
Phase III /pivotal confirmatory study Start	[***]
Phase III /pivotal confirmatory study Finish	[***]

**EXECUTION COPY** 

# AGREEMENT AND PLAN OF MERGER

This AGREEMENT AND PLAN OF MERGER (this "Agreement") is entered into on this 31st day of December, 2015 (the "Effective Date") by and between MeiraGTx Acquisition Corporation, a Delaware corporation ("Merger Sub"), BRI-Alzan Inc., a Delaware corporation (the "Company"), F-Prime Inc. (f/k/a Fidelity Biosciences Corp.), a Delaware corporation with the address of its principal office set forth on the signature page hereto ("Fidelity"), Gregory Petsko, an individual resident at the address set forth on the signature page hereto ("Ringe"), and Brandeis University, a not-for-profit corporation duly incorporated and existing under the laws of the Commonwealth of Massachusetts with the address of its principal office set forth on the signature page hereto ("Brandeis" and together with Fidelity, Petsko and Ringe, each, a "Seller" and, collectively, the "Sellers"), Fidelity, solely in its capacity as agent for the Sellers (the "Sellers' Representative"), and MeiraGTx Limited, a private limited company duly formed and existing under the laws of England and Wales (Company No. 9501998) and the sole shareholder of Merger Sub ("Parent"). Merger Sub, the Company, the Sellers and Parent may each be referred to herein individually as a "Party" and collectively as the "Parties." Capitalized terms used in this Agreement shall have the meanings ascribed to them in Section 1 herein.

### **RECITALS**

WHEREAS, the Sellers own all of the issued and outstanding shares of common stock, par value \$0.01 per share (the "Company Shares"), of the Company;

WHEREAS, the Company is party to that certain License Agreement, dated as of May 1, 2013 (the "License Agreement"), by and between the Company and Brandeis, for the commercial development, manufacture and distribution of products derived from the technology licensed under the License Agreement, a true and complete copy of which is attached hereto as <u>Exhibit A</u>; and

WHEREAS, Merger Sub and the Company believe it is in the best interests of their respective companies and the stockholders of their respective companies that the Company and Merger Sub combine into a single company through the statutory merger of Merger Sub with and into the Company (the "Merger"), with the Company surviving the Merger and Merger Sub ceasing to exist, such that the Company becomes a wholly-owned subsidiary of Parent and Parent thereby indirectly acquires the License Agreement and the Company's rights and obligations thereunder, in each case, upon the terms and subject to the conditions set forth herein.

#### **AGREEMENT**

NOW, THEREFORE, in consideration of the promises and mutual agreements and covenants contained herein, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, agree as follows:

### 1. DEFINITIONS.

- 1.1 "**409A Valuation**" has the meaning set forth in Section 6.4.5(b)(ii)(A).
- 1.2 "Accounting Firm" has the meaning set forth in Section 2.3.3(b).
- 1.3 "Action" has the meaning set forth in Section 7.2.2.
- 1.4 "Affiliate(s)" means, with respect to a Party, any Person that, directly or indirectly, through one or more intermediaries, controls, is controlled by or is under common control with such Party. For purposes of this definition, "control" and, with correlative meanings, the terms "controlled by" and "under common control with" means (i) the possession, directly or indirectly, of the power to direct the management or policies of a Person, whether through the ownership of voting securities or by contract relating to voting rights or corporate governance; or (ii) the ownership, directly or indirectly, of more than fifty percent (50%) of the voting securities or other ownership interest of a Person (or, with respect to a limited partnership or other similar entity, its general partner or controlling entity). For the avoidance of doubt, for purposes of this Agreement and the Ancillary Agreements, (a) the Company shall be an Affiliate of Parent from and after the Effective Time, (b) no Seller shall be an Affiliate of the Company or Parent from and after the Effective Time, and (c) the Company shall not be an Affiliate of Brandeis or any of Brandeis's Affiliates at any time.
  - 1.5 "**Agreement**" has the meaning set forth in the preamble.
- 1.6 "Ancillary Agreements" means, other than this Agreement, the agreements and instruments executed and delivered in connection with the transactions contemplated by this Agreement.
- 1.7 "Applicable Laws" means all federal, state, local or foreign laws, codes, statutes, ordinances, regulations, rules, requirements, guidance, or orders of any kind whatsoever pertaining to any Party, the Company Shares, the Parent Shares or any of the activities contemplated by this Agreement, including, without limitation, the FDCA, the Anti-Kickback Statute (42 U.S.C. § 1320a-7b et seq.), data security, confidentiality, and privacy laws, rules, regulations and standards, including, without limitation, the Fair Credit Reporting Act, 15 U.S.C. 1681 et seq. (including the Fair and Accurate Credit Transactions Act of 2003) and the PCI Security Standards Council's Payment Card Industry Data Security Standard, including, without limitation, the Payment Application Data Security Standards and all audit and filing requirements, and Tax laws, and any other regulations promulgated by any Governmental Authority, all as amended from time to time in the relevant territory.
  - 1.8 "BLA" means a Biologics License Application as defined in the FDCA and any equivalent foreign application, registration or certification.
- 1.9 "BLA Acceptance" means the written notification by the FDA or equivalent Governmental Authority for a country in the Territory that the BLA has met all the criteria for filing acceptance pursuant to 21 C.F.R. §314.101 or its foreign equivalent if such filing is outside the US.

- 1.10 "Brandeis" has the meaning set forth in the Recitals.
- 1.11 "**Business Day**" means any day except Saturday, Sunday, any day which shall be a federal legal holiday in the United States, or any day on which banking institutions in New York City are authorized or required by law or other governmental action to close.
  - 1.12 "Certificate of Merger" has the meaning set forth in Section 2.1.1.
  - 1.13 "Closing" has the meaning set forth in Section 2.4.
  - 1.14 "Closing Date" has the meaning set forth in Section 2.4.
  - 1.15 "Code" means the U.S. Internal Revenue Code of 1986, as amended, and the rules and regulations thereunder.
- 1.16 "Combination Product" means a product which comprises (a) a Product and (b) at least one other active ingredient (including a biologic product) or medical device.
- 1.17 "Commercially Reasonable Efforts" means with respect to the efforts to be expended by a Party with respect to any objective, reasonable, good faith efforts to accomplish such objective as a Person in the life sciences industry would normally use to accomplish a similar objective under similar circumstances, taking into consideration the stage of development or product life, present and future market potential, efficacy, safety, approved labeling or anticipated labeling, competitiveness of alternative products sold by Third Parties in the marketplace, patent and other proprietary positions, present and future regulatory environment, profitability (including royalties payable to licensors of patent or other intellectual property rights other than any royalty, milestone or other payment to be made under this Agreement) and past performance of a Product developed by such Party.
- 1.18 "Commercialization" and "Commercialize" means the activities carried out by or on behalf of a Party in distributing (including importing, transporting, warehousing, invoicing, handling and delivering Product to customers), promoting, marketing and selling Product, but does not include selling the Product for clinical trial purposes.
  - 1.19 "Company" has the meaning set forth in the preamble.
  - 1.20 "Company Assets" has the meaning set forth in Section 3.3.6.
  - 1.21 "Company Confidential Information" has the meaning set forth in Section 5.1.3.
  - 1.22 1.22 "Company Intellectual Property Rights" has the meaning set forth in Section 3.3.7.
  - 1.23 "Company Shares" has the meaning set forth in the Recitals.
- 1.24 "Competing Technology" means any materials, technology, technical and scientific information, improvements, methods, data (whether in vitro, in vivo, and whether in animals or humans), know-how, and expertise, for the treatment, prevention, or delay in onset of

amyotrophic lateral sclerosis (ALS) by providing one or more nonsense-mediated mRNA decay polypeptides to neuronal or glial cells to reduce FUS/TLS and/or TDP-43 toxicity as described in the claims in the Patent Rights pending or issued as of the Effective Date. For the avoidance of doubt, actions taken by Fidelity or any of its Affiliates (excluding any Seller other than Fidelity) related to proposed or actual investments, or actions taken by any of their or their Affiliates' partners, officers or representatives (in each case, excluding any Seller other than Fidelity) related to such proposed or actual investments, shall not be considered "consulting] with, render[ing] services for or otherwise engag[ing] in any business, endeavor or activity anywhere in the Territory for the development, manufacture, use or Commercialization of any Competing Technology" for purposes of Section 5.2(a) of this Agreement.

- 1.25 "**Confidential Information**" means technical, financial, manufacturing or marketing information, ideas, methods, developments, improvements, business plans, know-how, trade secrets or other proprietary information relating thereto, together with analyses, compilations, studies or other documents, records or data of a Party or its Affiliates, which contain or otherwise reflect or are generated from such information.
- 1.26 "Confidentiality Agreements" means (a) the Confidentiality Agreement dated as of June 15, 2015 by and between Kadmon Corporation, LLC, MeiraGTx, LLC and Fidelity, and (b) the Confidentiality Agreement dated as of November 2, 2015 by and between Parent and Brandeis.
- 1.27 "**Contracts**" means any and all contracts, agreements, leases, licenses, franchises, warranties, guaranties, mortgages, notes, bonds, options, warrants, rights, purchase orders, letter agreements, subscriptions, commitments, understandings and other obligations in each case, whether written or oral, proposed, contingent or otherwise, and includes any amendment, modification or supplement thereto.
- 1.28 "Control" means, with respect to any item of Company Intellectual Property Rights or Company Confidential Information, ownership of or possession of the right, whether by ownership or by license, to enforce, use, assign or practice such item of Company Intellectual Property Rights or Company Confidential Information.
  - 1.29 "Covered Person" has the meaning set forth in Section 3.3.9(m).
  - 1.30 "**Delaware Law**" has the meaning set forth in <u>Section 2.1</u>.
  - 1.31 "**Direct Claims**" has the meaning set forth in <u>Section 6.6</u>.
  - 1.32 "**Disqualification Event**" has the meaning set forth in <u>Section 3.3.9(m)</u>.
  - 1.33 "DFAR" has the meaning set forth in Section 3.3.9(l).
  - 1.34 "Effective Date" has the meaning set forth in the preamble.
  - 1.35 "Effective Time" has the meaning set forth in Section 2.1.1.

- 1.36 "Employee Benefit Plan" means each "employee benefit plan" (as such term is defined in Section 3(3) of ERISA) and each other employee benefit plan, program or arrangement, company or payroll practice, including without limitation severance pay, redundancy programs or practices, sick leave, vacation pay, salary continuation for disability, employment, consulting or other compensation agreements, retirement, pension, deferred compensation, bonus, stock purchase, stock appreciation rights, hospitalization, medical insurance, voluntary or other health insurance, life insurance, disability, death or sickness insurance and scholarship programs maintained, sponsored or contributed to by or on behalf of the Company or with respect to which the Company has or may have any Liability, including any Multiemployer Plan.
- 1.37 **"Encumbrance"** means any lien, mortgage, security interest, pledge, restriction on transferability or use, right of first refusal, defect of title, or other claim, charge or encumbrance of any nature whatsoever on any asset, property or property interest.
  - 1.38 "Environmental Laws" has the meaning set forth in Section 3.3.18.
  - 1.39 "Environmental Liabilities" has the meaning set forth in Section 3.3.18.
  - 1.40 "ERISA" means the Employee Retirement Income Security Act of 1974, as amended.
- 1.41 "ERISA Affiliate" means any entity that, together with the Company, would be deemed a "single employer" within the meaning of Section 4001(b) of ERISA or Sections 414(b), (c), (m), or (o) of the Code and the regulations thereunder.
  - 1.42 "Exchange Rate" has the meaning set forth in Section 7.12.1.
  - 1.43 "Expiration Date" has the meaning set forth in Section 6.1.
  - 1.44 "FAR" has the meaning set forth in Section 3.3.9(1).
  - 1.45 "FDA" means the United States Food and Drug Administration, and any successor agency(ies) or authority having substantially the same function.
  - 1.46 "FDCA" means the U.S. Federal Food, Drug and Cosmetic Act, as amended, 21 U.S.C. § 321, et seq.
  - 1.47 "Fidelity" has the meaning set forth in the preamble.
  - 1.48 "Fidelity Subscription Agreement" has the meaning set forth in Schedule 1.59.
- 1.49 "First Commercial Sale" means the first bona fide, arm's length sale by, on behalf of or under the authority of the Company, its Affiliates or sublicensees to a Third Party for end use or consumption in the Territory after the required marketing and pricing approval has been granted by the Pharmaceutical Product Regulatory Authority of such country. Sale of a Product to an Affiliate or sublicensee, unless the Affiliate or sublicensee is the end user of the Product, transfers or dispositions as samples or for charitable purposes (including, without limitation, pursuant to an early access, compassionate use, named patient, indigent access or patient assistance program), or transfers or dispositions for preclinical, clinical or regulatory purposes in furtherance of obtaining regulatory approval of the Product shall not constitute a First Commercial Sale.

- 1.50 "Governmental Authority" means any nation or government, any provincial, state, regional, local or other political subdivision thereof, any supranational organization of sovereign states, and any entity, department, commission, bureau, agency, authority, board, court, official or officer, domestic or foreign, exercising executive, judicial, regulatory or administrative functions of or pertaining to government, including the FDA.
- 1.51 "Government Contract" means any Contract entered into by the Company with any Governmental Authority or with any prime contractor or subcontractor (at any tier) relating to a Contract where any Governmental Authority is a party thereto. A task, purchase or delivery order under a Government Contract or any amendment, supplement or modification to a Government Contract shall not constitute a separate Government Contract for purposes of this definition, but shall be part of the Government Contract to which it relates.
  - 1.52 "Hazardous Materials" has the meaning set forth in Section 3.3.18.
  - 1.53 "**Indemnified Party**" has the meanings set forth in each of <u>Section 6.4</u> and <u>Section 6.5.1</u>.
  - 1.54 "**Indemnifying Party**" has the meaning set forth in Section 6.5.1.
- 1.55 "**Institutional Review Board**" means any domestic or foreign institutional review board or ethics committee overseeing any clinical trial involving the Product.
- 1.56 "**Intellectual Property Rights**" means all intellectual property rights, including (i) Patent Rights, (ii) trademarks, trademark registrations, trademark applications, service marks, service mark registrations, service mark applications and domain names, (iii) copyrights, copyright registrations and copyright applications, (iv) know-how, inventions (whether or not patentable), non-clinical data, pre-clinical data, in-vitro data, formulae, processes, methodologies, and trade secrets, and (v) all rights in all of the foregoing provided by Applicable Law.
  - 1.57 "**Interested Parties**" has the meaning set forth in <u>Section 3.3.17</u>.
  - 1.58 "**Inventors**" has the meaning set forth in <u>Section 3.5.2</u>.
  - 1.59 "Investment Agreements" means the Contracts listed on Schedule 1.59.
  - 1.60 "Know How" has the meaning given to such term in the License Agreement (as amended by the License Agreement Amendment).
- 1.61 "**Knowledge**" means all facts actually known, or which should have been reasonably known, by the relevant personnel with primary responsibility for the matter in question on a day to day basis, following reasonable investigation and inquiry by such personnel.
- 1.62 "**Liability**" means, collectively, any indebtedness, guaranty, endorsement, claim, loss, damage, deficiency, cost, expense, obligation or responsibility, fixed or unfixed, known or unknown, choate or inchoate, liquidated or unliquidated, secured or unsecured, direct or indirect, matured or unmatured, due or to become due, absolute or contingent, accrued or not accrued, and whether or not required to be reflected in the financial statements in accordance with U.S. or U.K., as applicable, generally accepted accounting principles.

- 1.63 "License Agreement" has the meaning set forth in the Recitals.
- 1.64 "License Agreement Amendment" has the meaning set forth in Section 4.1.5.
- 1.65 "Licensed Know How" means the Know How licensed to the Company under the License Agreement (as amended by the License Agreement Amendment).
- 1.66 "Licensed Patent Rights" means the Patent Rights licensed to the Company under the License Agreement (as amended by the License Agreement Amendment).
- 1.67 "**Losses**" means any and all losses, Liabilities, damages, claims, awards, judgments, Taxes, interest, penalties, costs and expenses (including, without limitation, attorneys' fees, experts' fees and other similar out-of-pocket expenses) actually suffered or incurred.
- 1.68 "Material Adverse Effect" means any change, circumstance or event that, individually or in the aggregate, has a material adverse effect on the Company, the Company Shares, or the Licensed Patent Rights; provided, however, that Material Adverse Effect shall exclude any adverse changes or conditions as and to the extent such changes or conditions relate to or result from: (a) the announcement of this Agreement or the pendency of the transactions contemplated hereby; (b) the execution, delivery or performance of this Agreement and the Ancillary Agreements; (c) general economic conditions or other conditions generally affecting the pharmaceutical industry which do not have a disproportionate impact on the Company, the Company Shares or the Licensed Patent Rights; (d) any change in Applicable Laws or the interpretation thereof by any Governmental Authority; or (e) any natural disaster, force majeure events or any acts of terrorism, sabotage, military action or war (whether or not declared) or any escalation or worsening thereof, except, in the case of the foregoing clauses (c) through (f), to the extent such event, change, development, circumstance, occurrence, effect or state of facts has had (or would reasonably be expected to have) a materially disproportionate adverse impact on the Company, taken as a whole, the Company, the Company Shares, or the Licensed Patent Rights, individually or in the agreement, as compared to other Persons in the industry in which the Company conducts its business.
  - 1.69 "Merger" has the meaning set forth in the Recitals.
  - 1.70 "Merger Sub" has the meaning set forth in the preamble.
  - 1.71 "Merger Sub Share" has the meaning set forth in Section 2.1.5(c).
  - 1.72 "Milestone Payment" has the meaning set forth in Section 2.3.1.
  - 1.73 "Multiemployer Plan" has the meaning provided in Section 3(37) of ERISA.
- 1.74 "**NDA**" means any New Drug Application under the FDCA (together with all subsequent submissions, supplements and amendments thereto, and any materials, documents or information referred to or relied upon thereby) seeking approval to market, sell or otherwise distribute a Product, in any formulation or dosage form, in the United States, and similar applications or filings in the countries within the Territory.

- 1.75 "**Net Sales**" means, with respect to a Product for any period, the aggregate gross amount billed or invoiced on sales of such Product during such period by the Company or its sublicensees in a particular country in the Territory to Third Parties (including wholesalers or distributors) in bona fide arm's-length transactions, less the following deductions, in each case related specifically to the Product and actually allowed and taken by or credited to such Third Parties:
  - (a) normal trade, cash or quantity discounts actually given;
- (b) chargeback payments, price reductions or rebates, retroactive or otherwise, imposed by, negotiated with or otherwise paid to governmental authorities or other payees;
- (c) Taxes, tariffs on sales (such as sales, value added, or use taxes), duties or other governmental charges levied on or measured by the sale of Products, whether absorbed by the Company or its Affiliates or paid by the payee to the extent added to the sale price and set forth separately as such in the total amount invoiced (provided that, in no event, will the deductions in this subsection (c) include franchise taxes or income taxes of any kind);
- (d) amounts repaid, credited or allowed or price adjustments by reason of rejections, defects, damaged Product or for the rejection or return of Product previously sold;
- (e) any consideration actually paid or payable for any delivery system related to a billed or invoiced sale of such Product, where, for purposes of this Net Sales definition, a "delivery system" means any delivery system comprising equipment, instrumentation, one or more devices, or other components designed to assist in the administration of such Product;
- (f) freight, insurance, shipping and handling or other transportation charges to the extent set forth separately as such in the total amount invoiced, as well as any fees for services provided by wholesalers and warehousing chains related to the distribution of such Product;
- (g) any royalties owed to Brandies under the License Agreement for sales of Product to any governmental authority for which such governmental authority is entitled to a royalty-free right pursuant 35 USC 202(c)(paragraph 4); and
  - (h) any other similar and customary deductions to the extent set forth separately as such in the total amount invoiced.

Net Sales shall not include transfers or dispositions for charitable, compassionate, promotional, pre-clinical, clinical, regulatory, or governmental purposes. Net Sales shall not include sales between or among the Parent and its Subsidiaries (including, after the Closing, the Company) or their sublicensees. Subject to the above, Net Sales shall be calculated in accordance with U.K. GAAP, consistently applied with the past practice of the Parent and its Subsidiaries.

For Net Sales of a Product sold or supplied as a Combination Product, the Net Sales of such a Combination Product will be determined, subject to the provisions set forth below in this Section 1.74, by multiplying the actual Net Sales of such Combination Product in a particular country in the Territory by the fraction of A/(A+B), where A is the average gross amount billed or invoiced per unit of such Product in such country in the Territory during the period in respect of which Net Sales are being calculated of the Product sold separately and B is the total average gross amount billed or invoiced per unit in such country in the Territory of the other active ingredient (including a biologic product) or device included in the Combination Product during the period in respect of which Net Sales are being calculated, when sold separately. If neither the Product nor the other active ingredient (including a biologic product) or device included in the Combination Product are sold separately as a monotherapy in such country in the Territory during the period in respect of which Net Sales are being calculated, then the Company or the Parent, on the one hand, and the Sellers' Representative on the other, shall agree in writing on the fair market value of the other active ingredient (including a biologic product) or device included in the Combination Product that is to be deducted from the Net Sales of the Combination Product in determining the Net Sales of the Product contained in the Combination Product; provided, however, if such Parties shall be unable to agree in writing on the fair market value of such other active ingredient (including a biologic product) or device within thirty (30) days from the date of First Commercial Sale of such Combination Product, then the parties shall request that the Accounting Firm resolve such disagreement in accordance with the procedures set forth in Section 2.3.3 of this Agreement, which determination by the Accounting Firm shall be final, binding and conclusive on the Company, the Se

- 1.76 "Objection Notice" has the meaning set forth in Section 2.3.3(b).
- 1.77 "Parent" has the meaning set forth in the preamble.
- 1.78 "Parent's Accounting Principles" has the meaning set forth in Section 2.3.2(c).
- 1.79 "Parent Indemnified Party" has the meaning set forth in Section 6.3.1.
- 1.80 "Parent Shares" has the meaning set forth in Section 2.1.5(a).
- 1.81 "Parent Shareholder Agreement" has the meaning set forth in Schedule 4.1.1.
- 1.82 "**Patent Files**" mean copies (or originals, where available to the Company or its agents or Affiliates) of the following to the extent comprising or relating to Licensed Patent Rights: (a) all patents, patent applications, assignments and correspondence to and from any country in the Territory (whether or not to or from the Company); and (b) to the extent that the same are in existence and related to the items in clause (a), all files, records, workbooks (including, without limitation, laboratory notebooks), correspondence, data, notes and information in the possession or Control of the Company or its agents.
  - 1.83 "Patent Rights" has the meaning given to such term in the License Agreement (as amended by the License Agreement Amendment).
- 1.84 "**Person**" means any individual, corporation, partnership, joint venture, limited liability company, joint stock company, trust or unincorporated organization or Governmental Authority.
  - 1.85 "Petsko" has the meaning set forth in the preamble.

- 1.86 "Pharmaceutical Product Regulatory Authority" means any Governmental Authority that is concerned with the safety, efficacy, reliability, manufacture, investigation, sale or marketing of pharmaceuticals or medical products, and from which permission is needed to market any such products, including the FDA.
- 1.87 "**Phase III Study**" means any controlled study in humans of the efficacy and safety of a product which is conducted after Phase II Study has been completed and which is prospectively designed to demonstrate statistically whether the product is safe and effective for use in a particular indication and is usually intended to be sufficient to support registration of the Product.
- 1.88 "Preclinical Stud(y/ies)" means all studies and other testing, including any animal or other non-clinical studies and testing, not conducted on humans.
- 1.89 "**Pre-Closing Tax Period**" means any Tax period ending on or before the Closing Date; and, with respect to a Straddle Period, the portion of such Tax period ending at the end of the Closing Date.
  - 1.90 "Privacy Practices" has the meaning set forth in Section 3.3.9(h).
- 1.91 "**Product**" means a product for the therapeutic or prophylactic treatment of amyotrophic lateral sclerosis (ALS) that is covered by a Valid Claim of the Licensed Patent Rights.
- 1.92 "**Post-Closing Tax Period**" means any taxable period beginning after the Closing Date and, with respect to any taxable period beginning before and ending after the Closing Date, the portion of such taxable period beginning after the Closing Date.
  - 1.93 "Post-Closing Taxes" means Taxes of the Company for any Post-Closing Tax Period.
- 1.94 "Qualified Financing" shall mean an equity financing of the Parent in which the Parent issues ordinary or preferred shares in a transaction or series of transactions, excluding pursuant to an employee benefit plan of Parent.
- 1.95 "**Registrations**" means, with respect to any jurisdiction, any and all of the regulatory approvals, licenses, registrations, agreements, permits, exemptions, clearances, certificates, consents, authorizations, other permissions, and requests for approval for, and supplements or amendments to, the foregoing Controlled by the Company or its Affiliates relating to the Product issued by any Governmental Authority, necessary or useful to study, manufacture, or Commercialize a Product in a country in the Territory, including where applicable, applications for pricing and reimbursement approval.
- 1.96 "Regulatory Documentation" means any and all applications to or from the FDA or any other Governmental Authority for approvals (including all drug approval applications, NDAs, NDA amendments, supplemental NDAs, BLAs, BLA amendments, supplemental BLAs, CTAs and CTA amendments), registrations, licenses, authorizations and approvals (including all Registrations), submissions, notifications, and Preclinical Study and clinical study authorization applications or notifications (including all supporting files, writings, data, studies and reports)

prepared for submission to a Governmental Authority or research Institutional Review Board with a view to the granting of any Registration (investigational new drug application or clinical trial application), approvals granted by or received from the FDA or any other Governmental Authority (including marketing approvals, variations and pricing applications) or other marketing authorization or approval, and any correspondence to or with the FDA or any other Governmental Authority with respect to Product as it relates to the Territory (including minutes, tracking logs, internal meeting minutes and contact reports, and official contact reports relating to any communications, written or verbal, with any Governmental Authority), and all data contained in any of the foregoing, including all regulatory drug lists, advertising and promotion documents, adverse event files and complaint files relating to the Product.

- 1.97 "Report" has the meaning set forth in Section 2.3.2(a).
- 1.98 "**Representatives**" means, with respect to any Party, such Party's counsel, accountants, financial advisors, lenders and other agents and representatives.
  - 1.99 "Restricted Party" means each of Fidelity, Petsko and Ringe who are subject to the restrictions contained in Section 5.2 of this Agreement.
  - 1.100 "**Return Date**" has the meaning set forth in <u>Section 6.4.5(b)</u>.
  - 1.101 "Ringe" has the meaning set forth in the preamble.
  - 1.102 "Royalty Payment" has the meaning set forth in Section 2.3.2(a).
  - 1.103 "Royalty Period" has the meaning set forth in Section 2.3.2(a).
  - 1.104 "Securities Act" mean the U.S. Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.
  - 1.105 "Sellers" has the meaning set forth in the preamble.
  - 1.106 "Seller Indemnified Party" has the meaning set forth in Section 6.2.
  - 1.107 "**Sellers' Representative**" has the meaning set forth in the preamble.
  - 1.108 "Special Representations" has the meaning set forth in Section 6.1.
  - 1.109 "Straddle Period" has the meaning set forth in Section 5.4.2.
- 1.110 "Subsidiary" means any corporation, partnership, limited liability company or other legal entity of which the Company (either alone or together with any other Subsidiary) owns any stock or other equity or partnership interests the holders of which are generally entitled to vote for the election of the board of directors or other governing body of such corporation or other legal entity or of which such corporation or other legal entity controls the management.
  - 1.111 "Surviving Corporation" has the meaning set forth in Section 2.1.

- 1.112 "Tax" or "Taxes" means (a) any and all federal, state, local, or non-U.S. income, gross receipts, license, payroll, employment, excise, severance, stamp, occupation, premium, windfall profits, environmental, customs duties, capital stock, franchise, profits, withholding, social security (or similar), unemployment, disability, real property, gross margins, personal property, sales, use, transfer, registration, alternative or add-on minimum, estimated, or other tax of any kind whatsoever, including any interest, fine, penalty, or addition thereto, (b) any liability for the payment of any amounts of the type described in clause (a) as a result of being a member of an affiliated, consolidated, combined, unitary, or aggregate group for any taxable period, and (c) any liability for the payment of any amounts of the type described in clause (a) or (b) as a result of being a transferee of or successor to any Person or as a result of an obligation to indemnify any Person.
  - 1.113 "Tax Claim" has the meaning set forth in Section 5.4.3.
- 1.114 "**Tax Return**" means any report, return, declaration or other information or filing, including any amendments thereto, supplied or required to be supplied to any Taxing Authority with respect to Taxes, including information returns, claims for refund and any documents with respect to or accompanying payments of estimated Taxes.
- 1.115 "Taxing Authority" means any federal, state, or local Governmental Authority responsible for the assessment, collection, imposition or administration of any Tax.
- 1.116 "**Technical Information**" means any and all technical and/or scientific data and information, including any chemical, formulation, structural, functional biological, chemical, pharmacological, toxicological, pharmaceutical, physical, analytical, process, pre-clinical, clinical, assay, control, safety, manufacturing and quality control data and information, and all copyrights, trade secret rights and other Intellectual Property Rights relating to any of the foregoing.
- 1.117 "**Territory**" means the US, Australia, Canada and Europe and any other jurisdiction in which the Company is granted orphan drug or other regulatory exclusivity.
  - 1.118 "Third Part(y/ies)" means any Person(s) other than Company and its Affiliates and Merger Sub, the Parent and their respective Affiliates.
  - 1.119 "Third Party Claim" has the meaning set forth in Section 6.5.1.
  - 1.120 "**Transaction Documents**" means this Agreement and the Ancillary Agreements.
  - 1.121 "United Kingdom" or "U.K." means the United Kingdom of Great Britain and Northern Ireland.
  - 1.122 "U.K. GAAP" means United Kingdom generally accepted accounting principles.
  - 1.123 "United States" or "U.S." means the United States of America, its territories, protectorates and possessions.
  - 1.124 "U.S. GAAP" means United States generally accepted accounting principles.

1.125 "Valid Claim" means any claim in any (a) issued and unexpired patent of the Licensed Patent Rights that has not been abandoned in accordance with the terms of the License Agreement, has not been rejected, revoked, held unenforceable, unpatentable or invalid in a final decision of a court or other Governmental Authority of competent jurisdiction from which no appeal has been or can be taken or (b) pending patent application among the Licensed Patent Rights that have been pending for no more than four (4) years from the first priority date claimed in such patent application.

### 2. THE MERGER.

- 2.1 **The Merger**. At the Effective Time, subject to the terms and conditions set forth in this Agreement and the applicable provisions of the Delaware General Corporation Law ("**Delaware Law**"), Merger Sub shall be merged with and into the Company, the separate corporate existence of Merger Sub shall cease and the Company shall continue as the surviving corporation. The Company as the surviving corporation after the Merger is hereinafter sometimes referred to as the "**Surviving Corporation**."
- 2.1.1 <u>Effective Time</u>. At the Closing, the Parties shall file a certificate of merger in substantially the form attached hereto as <u>Exhibit B</u> (the "**Certificate of Merger**") and executed in accordance with the relevant provisions of Delaware Law and make such other filings and recordings as required under Delaware Law. The Merger shall become effective at such time as is specified in the Certificate of Merger as is duly filed with the Delaware Secretary of State (the "**Effective Time**").
- 2.1.2 <u>Effect of Merger</u>. At the Effective Time, the effect of the Merger shall be as provided in this Agreement, the Certificate of Merger and the applicable provisions of Delaware Law. Without limiting the generality of the foregoing, and subject thereto, at the Effective Time, all the property, rights, privileges, powers and franchises of the Company and Merger Sub shall vest in the Surviving Corporation, and all debts, Liabilities and duties of the Company and Merger Sub shall become the debts, Liabilities and duties of the Surviving Corporation.
- 2.1.3 <u>Charter; Bylaws</u>. At the Effective Time, the Certificate of Incorporation of the Surviving Corporation shall be amended as provided in the Certificate of Merger. The Bylaws of Merger Sub, as in effect immediately prior to the Effective Time, shall be the Bylaws of the Surviving Corporation until thereafter amended.
- 2.1.4 <u>Directors; Officers</u>. At the Effective Time, the directors of Merger Sub immediately prior to the Effective Time shall be the directors of the Surviving Corporation, to hold office until such time as such directors resign, are removed or their respective successors are duly elected or appointed and qualified. The officers of Merger Sub immediately prior to the Effective Time shall be the officers of the Surviving Corporation, to hold office until such time as such officers resign, are removed or their respective successors are duly elected or appointed and qualified.
  - 2.1.5 Effect of Merger on the Capital Stock of the Constituent Corporations.
- (a) At the Effective Time, by virtue of the Merger and without any action on the part of Merger Sub, the Company or the Sellers, upon the terms and subject to the conditions set forth in this Agreement, each Company Share issued and outstanding immediately prior to the Effective Time will be cancelled and extinguished and be converted automatically into

the right to receive, credited as fully paid, 15 A ordinary shares of £0.0001 each in the capital of the Parent (the "**Parent Shares**"), which Parent Shares, for the avoidance of doubt, the Parent is issuing to the Sellers in consideration for the Merger. At the Effective Time, upon the terms and subject to the conditions set forth in this Agreement, Parent will, and Merger Sub hereby procures that Parent will, allot and issue the Parent Shares to the Sellers as set forth on Schedule 2.1.5. In no event, shall the Parent Shares to be issued to the Sellers under this Agreement in respect of the Merger exceed, credited as fully paid, in aggregate 30,000 A ordinary shares of £0.0001 each in the capital of the Parent. The Parent Shares shall be distributed amongst the Sellers as set forth on Schedule 2.1.5.

- (b) Each outstanding Company Share owned by the Company as treasury stock or authorized but currently unissued Company Shares immediately prior to the Effective Time will, by virtue of the Merger, and without any action on the part of the holder thereof, no longer be outstanding, be cancelled and extinguished without payment of any Merger Consideration therefor and will cease to exist.
- (c) At the Effective Time, by virtue of the Merger and without any action on the part of the Parent, Merger Sub, the Company, the Sellers, or any other Person, upon the terms and subject to the conditions set forth in this Agreement, each share of common stock, par value \$0.01 per share, of Merger Sub (each, a "Merger Sub Share") that is outstanding immediately prior to the Effective Time shall be cancelled and extinguished and be converted automatically into, and shall thereupon represent, one fully paid and non-assessable share of common stock, par value \$0.01 per share, of the Surviving Corporation, with the same rights, powers and privileges as the Merger Sub Shares so converted and shall thereupon constitute the only outstanding shares of capital stock of the Surviving Corporation, to be held exclusively by the Parent.

### 2.1.6 Stock Certificates Evidencing Company Shares.

- (a) At the Effective Time, (i) no holder of record of a stock certificate that immediately prior to the Effective Time represented outstanding Company Shares shall have any rights as a stockholder of the Company other than the right to receive the applicable portion of the Parent Shares as set forth above in Section 2.1.5(a) in this Agreement, and (ii) each stock certificate representing any outstanding Company Shares shall thereafter represent only the right to receive the applicable portion of the Parent Shares as set forth above in Section 2.1.5(a) in this Agreement.
- (b) In the event any stock certificate representing any Company Shares shall have been lost, stolen or destroyed, upon the making of an affidavit of that fact by such Seller, the Parent shall issue to the Seller who is the record holder of such stock certificate representing any Company Shares a certificate evidencing such Seller's applicable portion of the Parent Shares; *provided*, *however*, that the Parent or the Surviving Corporation may, in its discretion and as a condition precedent to the payment of such consideration, require such Seller to indemnify the Parent and the Surviving Corporation against any claim that may be made against Merger Sub or the Surviving Corporation with respect to such stock certificate representing any Company Shares.

(c) At the Effective Time, the stock transfer books of the Company shall be closed, and there shall thereafter be no further registration of transfers of shares of Company Shares outstanding immediately prior to the Effective Time on the records of the Company. After the Effective Time, no transfer of such Company Shares shall thereafter be made on the stock transfer books of the Surviving Corporation.

### 2.2 Issuance of Merger Sub Share; Procurement of Parent Shares.

- 2.2.1 <u>Issuance of Merger Sub Share</u>. At the Closing and immediately prior to the Effective Time, Merger Sub shall, in consideration for the Parent issuing the Parent Shares in accordance with the provisions <u>Section 2.1.5(a)</u> (which Parent Shares, for the avoidance of doubt, the Parent is issuing to the Sellers in consideration for the Merger), issue to the Parent, one Merger Sub Share, which Merger Sub Share shall be duly authorized, validly issued, fully paid and non-assessable upon issuance.
- 2.2.2 <u>Procurement of the Issue of Parent Shares</u>. At the Effective Time, Merger Sub shall, in consideration for the Merger and in exchange for the issuance of a Merger Sub Share, procure that the Parent issues to the Sellers, credited as fully paid, the Parent Shares in accordance with the provisions of <u>Section 2.1.5(a)</u> of this Agreement (which Parent Shares, for the avoidance of doubt, the Parent is issuing to the Sellers in consideration for the Merger). In addition, Merger Sub shall procure that the Sellers are entered into the register of members of the Parent in respect of the number of Parent Shares to be issued to each such Seller pursuant to <u>Section 2.1.5(a)</u>.
- 2.3 **Contingent Payments.** In addition to the issuance of the Parent Shares, the Parent shall make, or cause the Company to make, to the Sellers or the Sellers' Representative, as herein set forth in this <u>Section 2.3</u>, the payments described in this <u>Section 2.3</u> as additional consideration for the Merger (the "**Contingent Payments**" and together with the Parent Shares, the "**Merger Consideration**") if, and at such times as, herein provided.
- 2.3.1 <u>Milestone Payments</u>. The following cash payments (each, a "**Milestone Payment**") to the Sellers in accordance with the payment instructions set forth on <u>Schedule 2.3.1</u>, each of which Milestone Payments shall be allocated amongst the Sellers in accordance with the proportions set forth on such <u>Schedule 2.3.1</u>:
- (a) [\*\*\*] dollars (US\$[\*\*\*]) to be paid, if at all, by wire transfer of immediately available funds within [\*\*\*] ([\*\*\*]) Business Days following [\*\*\*]; and
- (b) [\*\*\*] dollars (US\$[\*\*\*]) to be paid, if at all, by wire transfer of immediately available funds within [\*\*\*] ([\*\*\*]) Business Days following [\*\*\*].

Under no circumstances shall Parent or the Company be obligated under this <u>Section 2.3.1</u> to make Milestone Payments to the Sellers in excess of four million five hundred thousand dollars (US\$4,500,000) in the aggregate.

### 2.3.2 Royalty Payments.

- (a) For so long as there is at least one Valid Claim or orphan drug or other regulatory exclusivity in effect following the First Commercial Sale of any Product (the "Royalty Period") in any country within the Territory, an annual royalty payment (the "Royalty Payment") equal to [\*\*\*] percent ([\*\*\*]%) of annual Net Sales of such Product in such country within the Territory. Within [\*\*\*] ([\*\*\*]) days after the end of each calendar quarter during the Royalty Period, the Parent or its designee shall deliver a report (each a "Report") to the Sellers' Representative specifying the Net Sales by Product and by country in the Territory during the just completed calendar quarter for the applicable Royalty Period, and the actual aggregate amount payable to the Sellers' Representative on behalf of the Sellers on account of sales of any Product during such calendar quarter in the Royalty Period, which Report will provide the Sellers' Representative with calculations of the amount of the Royalty Payment in sufficient detail to enable the Sellers' Representative to review Net Sales of each Product for the period and the amount of the Royalty Payment paid. Subject to Section 2.3.3(b), any amounts payable by or on behalf of the Parent under this Section 2.3.2 shall be due and payable within [\*\*\*] ([\*\*\*]) days after the end of each calendar quarter during the applicable Royalty Period. Following the Royalty Period in respect of a Product, no additional Royalty Payment shall be due and owing in respect of such Product except for any Royalty Payment in respect of such Product that was accrued but unpaid during the Royalty Period.
- (b) All cash payments to be made by the Parent, the Company or one of their respective Affiliates under this <u>Section 2.3.2</u> will be made to the Sellers' Representative, as agent for the Sellers, in U.S. dollars by wire transfer to a single bank account specified on <u>Schedule 2.3.2</u> attached hereto or to such bank account as the Sellers' Representative may subsequently designate in writing to the Parent or the Company.
- (c) From and after the Closing Date, the Parent and the Company shall, and shall cause their Affiliates and their Affiliates' respective successors and assigns to determine Net Sales as follows:
- (i) The Parent, the Company and their Affiliates shall use accounting principles, methods and practices (including the application of U.K. GAAP) that it determines, in consultation with its advisors, to be consistent with U.K. GAAP (the "Parent's Accounting Principles") and shall not be required under this Agreement or otherwise to prepare the Report consistent with the historical accounting principles, methods and practices (including the application of U.S. GAAP) used by the Sellers or the Company prior to the Closing Date.
- (ii) The Company and its Affiliates (to the extent licensees or sublicensees of any Licensed Patent Rights) shall use Commercially Reasonable Efforts to operate and conduct the development, manufacture and/or Commercialization of the Licensed Patent Rights and any Product.

### 2.3.3 Records and Audits.

(a) The Company shall keep, and shall cause each of its Affiliates (to the extent licensees or sublicensees of any Licensed Patent Rights) and licensees, to keep adequate books and records of accounting for the purpose of calculating all Royalty Payments payable to the Sellers under Section 2.3.2. For the seven (7) years next following the end of the calendar year to which each shall pertain, such books and records of accounting (including those of the Company's applicable Affiliates and licensees) shall be kept at each of their principal place of business and shall be open for inspection at reasonable times and upon reasonable notice by the

Accounting Firm for the sole purpose of inspecting the Royalty Payments due to the Sellers under this Agreement. In no event shall such inspections be conducted hereunder more frequently than once every twelve (12) months. The Accounting Firm must have executed and delivered to the Company and its Affiliates (to the extent licensees or sublicensees of any Licensed Patent Rights) or licensees, a confidentiality agreement as reasonably requested by the Company, which shall include provisions limiting the Accounting Firm's disclosure to the Sellers' Representative and the Sellers to only the results and basis for such results of such inspection. The results of such inspection, if any, shall be binding on all Parties. Any underpayments shall be paid by the Company within thirty (30) days of notification of the results of such inspection. Any overpayments shall be fully creditable against amounts payable in subsequent payment periods. Sellers' Representative shall pay for such inspections, except that in the event there is any upward adjustment in aggregate Royalty Payments payable for any calendar year shown by such inspection of more than five percent (5%) of the amount paid, in which case, the Company shall reimburse Sellers' Representative for any reasonable out-of-pocket costs of the Accounting Firm.

(b) Each Report delivered pursuant to Section 2.3.2 shall be final, binding and conclusive, unless the Sellers' Representative notifies the Company and the Parent in writing of any disagreement therewith (an "Objection Notice") within thirty (30) days after its receipt thereof, specifying (a) those items as to which there is disagreement and (b) a reasonably detailed description of the basis, nature, dollar amount and extent of the dispute or disagreement. If the Sellers' Representatives delivers an Objection Notice within such 30 day- period, then for a period of ten (10) Business Days from the date of delivery of the Objection Notice, the Company shall afford the Sellers' Representative and its Representatives with reasonable access during normal business hours to the books and records of the Company or its Affiliates (to the extent licensees or sublicensees of any Licensed Patent Rights) and its licensees so as to enable its review of the applicable Report and the information contained therein. The Company and the Sellers' Representative shall attempt in good faith to resolve such dispute, and any resolution by them as to any disputed amounts shall be final, binding and conclusive. If the Company and the Sellers' Representative are unable to resolve all disputes reflected in the Objection Notice within ten (10) Business Days after the date of delivery of the Objection Notice (or such longer period as the Company and the Sellers' Representative may mutually agree upon), then the Company shall request that Ernst & Young LLP or such other independent certified public accounting firm of national recognition as mutually agreed upon by the Company and the Sellers' Representative (the "Accounting Firm") to resolve any remaining disagreements. The Company and the Sellers' Representative shall use their commercially reasonable efforts to cause the Accounting Firm to make its determination within thirty (30) days of its engagement for such purpose. The determination by the Accounting Firm shall be final, binding and conclusive on the Company, the Sellers' Representative and the Sellers and shall not be appealable. The Company and the Sellers' Representative shall deliver to the Accounting Firm all work papers and back-up materials relating to the unresolved disputes requested by the Accounting Firm to the extent available to the Company and the Sellers' Representative and their respective Representatives. The Company and the Sellers' Representative shall be afforded the opportunity to present to the Accounting Firm any material related to the unresolved disputes and to discuss the issues with the Accounting Firm; provided, however, that no such presentation or discussion shall occur without the presence of Representatives of the Company and the Sellers' Representative. The determination of the Accounting Firm shall be limited to the disagreements submitted to the Accounting Firm, Upon resolution by the Accounting Firm to its satisfaction of all such disputed matters, the Accounting

Firm shall cause to be prepared and shall deliver to the Company and the Sellers' Representative a final Report setting forth the Net Sales for each Product by country in the Territory in dispute as specified in the Objection Notice in respect of the calendar quarter at issue in the disputed Report, and the date of such delivery by the Accounting Firm shall be deemed the date on which the Report and the Net Sales for the applicable Products in the Territory in respect of the calendar quarter at issue in the disputed Report shall become final, binding and conclusive.

- (c) The fees, costs and expenses of the Accounting Firm pursuant to <u>Section 2.3.3(b)</u> shall be allocated between the Company or the Parent, on the one hand, and the Sellers' Representative, on the other hand, in the same proportion that the aggregate amount of the disputed items that are unsuccessfully disputed by such Party (as finally determined by the Accounting Firm) bears to the total amount of disputed items submitted.
- (d) The Company, its Affiliates (to the extent licensees or sublicensees of any Licensed Patent Rights) and licensees shall not be required under this Agreement to maintain books and records in respect of Royalty Payments or Net Sales of any Product for more than seven (7) years following the end of any calendar year.
- (e) All financial information subject to review under this <u>Section 2.3</u> shall be held by each Party in accordance with the confidentiality and non-use provisions of this Agreement, and shall cause its accounting firm to enter into an acceptable confidentiality agreement with the Company and/or its Affiliates obligating it to retain all such information in confidence pursuant to such confidentiality agreement.
- (f) The resolution of any claim or dispute in respect of Net Sales or any Royalty Payment shall be resolved as provided in this Section 2.3.3 and shall not be subject to any other dispute resolution provision (if any) provided for in this Agreement.
- 2.3.4 No Implied Rights. The right of the Sellers (directly or through the Sellers' Representative) to receive any Milestone Payment or Royalty Payment (i) is solely a contractual right and is not a security for purposes of any federal or state securities laws (and shall confer upon the Sellers only the rights of a general unsecured creditor under Applicable Law); (ii) will not be represented by any form of certificate or instrument; (iii) does not give the Sellers' Representative or Sellers any dividend rights, voting rights, liquidation rights, preemptive rights or other rights including, without limitation, any rights with respect to the operation or conduct of the business of the Company or the Company from and after the Closing; and (iv) may not be sold, assigned, pledged, gifted, conveyed, transferred or otherwise disposed.
- 2.4 **Closing**. The closing of the Merger hereunder shall be conducted telephonically and/or via email, facsimile transfer or other similar means of correspondence (the "**Closing**") concurrently with the execution and delivery of this Agreement on the Effective Date (the date of Closing, the "**Closing Date**"), and shall be deemed to have taken place at the offices of DLA Piper LLP (US) in New York City or at such other place as the Parties may mutually agree. Subject to the terms and conditions of this Agreement, at the Closing, (i) Merger Sub will issue one Merger Sub Share to the Parent in consideration for the Parent is issuing the Parent Shares in accordance with the provisions Section 2.1.5(a) (which Parent Shares, for the avoidance of doubt, the Parent is issuing to the Sellers in consideration for the Merger), which Merger Sub Share shall be duly authorized, validly issued, fully-paid and non-assessable; (ii) the Parent will issue, subject to the

filing of the Certificate of Merger as provided in Section 2.1.1 of this Agreement, the Parent Shares to the Sellers (which Parent Shares, for the avoidance of doubt, the Parent is issuing to the Sellers in consideration for the Merger), credited as fully paid, in accordance with Section 2.1.5(a) of this Agreement, which shall be allocated amongst the Sellers as set forth on Schedule 2.1.5, in exchange for the issue of one Merger Sub Share by Merger Sub; and (iii) the Parties will exchange (or cause to be exchanged) the certificates and/or other documents, or do, or cause to be done, all of the things respectively required of each Party as specified in Article 4 herein.

- 2.5 **Withholding.** Notwithstanding any other provision of this Agreement, Merger Sub, the Parent or, following the Effective Time, the Company, as the case may be, shall be entitled to withhold, or cause to be withheld, any and all amounts paid or deemed paid by it to any Person as a result of the transactions contemplated by this Agreement, including from any Contingent Payments, that it reasonably believes are required to be withheld under Applicable Law. To the extent such amounts are so deducted and withheld and paid over to the applicable Governmental Authority, such amounts shall be treated for all purposes of this Agreement as having been paid to the Person to whom such amounts would otherwise have been paid and the payor Party shall secure and, from time to time (if and as applicable), send to the payee Party evidence in its possession of such payment.
- 2.6 **Allocation of Company Expenses.** From and after the Effective Time, all accounts payable or other expenses of the Company (the "**Company Expenses**") in respect of the periods prior to and following the Effective Time shall be prorated and apportioned as follows:
  - (a) to Fidelity for all Company Expenses incurred in respect of any period prior to the Effective Time (which shall include the Closing
- (b) to Parent and the Surviving Corporation for all Company Expenses incurred in respect of any period from and after the Effective Time.

The payment of any Company Expenses subject to this <u>Section 2.6</u> shall be the responsibility of the Party required to pay such Company Expense pursuant to this <u>Section 2.6</u>; provided, however, that Parent or the Surviving Corporation shall be entitled to pay any Company Expense allocable to Fidelity pursuant to this <u>Section 2.6</u> and then, upon submission of an invoice or other reasonable documentation evidencing the applicable Company Expense, to be reimbursed for such Company Expense from Fidelity promptly (but within any event within 30 days) following submission of such invoice or other documentation evidencing such Company Expense. Each of Fidelity, on the one hand, and Parent and the Surviving Corporation, on the other, shall use Commercially Reasonable Efforts to make payment of any Company Expenses submitted for payment by such Party pursuant to this <u>Section 2.6</u> when the payment of such Company Expense is due.

### 3. REPRESENTATIONS AND WARRANTIES.

Date), and

- 3.1 Representations and Warranties of Merger Sub. Merger Sub hereby represents and warrants to the Sellers that as of the Closing Date:
- 3.1.1 <u>Authorization</u>. The execution, delivery and performance of this Agreement and each of the Ancillary Agreements to which it is or will be a party have been duly authorized by the Board of Directors and the sole stockholder of Merger Sub. No other action or approval on the part of Merger Sub or its Affiliates is required for the execution, delivery and performance of this Agreement by Merger Sub other than those which shall have already been made or obtained.

- 3.1.2 <u>Organization</u>. Merger Sub is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware. Merger Sub has all requisite power and authority to own, lease and operate the properties and assets it currently owns, leases and operates and to carry on its business and is duly qualified to transact business and is in good standing in each jurisdiction wherein the nature of the business conducted by Merger Sub as of the Closing Date or the ownership of its assets makes such qualification necessary. Merger Sub has previously made available to the Sellers true, correct and complete copies of its certificate of incorporation and bylaws.
- 3.1.3 <u>Power and Authority</u>. Merger Sub has the power and authority to execute and deliver this Agreement and the Ancillary Agreements to which it is or will be a party and to perform its obligations hereunder and thereunder. This Agreement and the Ancillary Agreements to which it is or will be a party have been duly executed and delivered by Merger Sub, and constitute the legal, valid and binding obligations of Merger Sub, enforceable against it in accordance with their terms except as such enforceability may be limited by bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' rights generally and by general principles of equity.
- 3.1.4 Non-Contravention. The execution, delivery and performance by Merger Sub of this Agreement and the Ancillary Agreements to which it is or will be a party and the consummation of the transactions contemplated by this Agreement and the Ancillary Agreements to which it is or will be a party do not: (a) violate, conflict with, result in any material breach of, or constitute a default (or an event that, with notice or lapse of time or both, would constitute a default) under (i) any Contract to which Merger Sub is a party, (ii) the provisions of its certificate of incorporation or bylaws, or (iii) any order, writ, injunction or decree of any Governmental Authority entered against it or by which any of its property is bound that would adversely affect Merger Sub's ability to consummate the transactions contemplated by this Agreement and the Ancillary Agreements; or (b) violate any Applicable Laws. There is no consent, approval, order or authorization of or from, or registration, notification, declaration or filing to or with, any Governmental Authority that is required by Merger Sub in connection with the execution, delivery or performance by Merger Sub of this Agreement and the Ancillary Agreements to which it is or will be a party or the consummation of the transactions contemplated hereby and thereby.
- 3.1.5 <u>Litigation</u>. There is no litigation or proceeding (including, but not limited to arbitration), in law or in equity, and there are no proceedings or governmental investigations before any commission or other administrative authority or Governmental Authority, pending, or, to Merger Sub's Knowledge, threatened, against Merger Sub or with respect to this Agreement or the consummation of the transactions contemplated hereby.
- 3.1.6 <u>Brokers</u>. No broker, investment banker, agent, finder or other intermediary acting on behalf of Merger Sub or under the authority thereof, is or will be entitled to any broker's or finder's fee or any other commission or similar fee directly or indirectly in connection with the transactions contemplated under this Agreement.

- 3.1.7 <u>Compliance with Applicable Laws</u>. Merger Sub is, and has been since its formation, in compliance with all Applicable Laws in all material respects.
  - 3.2 **Representations and Warranties of the Parent**. The Parent hereby represents and warrants to the Sellers that as of the Closing Date:
- 3.2.1 <u>Authorization</u>. The Parent has all necessary consents and authorizations to enter into and perform its obligations under this Agreement and each of the Ancillary Agreements to which it is or will be a party.
  - 3.2.2 Organization. The Parent is a private company limited by shares duly incorporated in England and Wales.
- 3.2.3 Parent Capitalization; Parent Shares. Schedule 3.2.3 sets forth the entire issued share capital of the Parent as of immediately prior to the Closing. All the issued shares of the Parent as of immediately prior to the Closing set forth on Schedule 3.2.3 have been properly allotted and are fully paid up and were issued in conformity with all Applicable Laws, including U.S. federal securities Applicable Laws. The issued shares of the Parent as of immediately prior to the Closing set forth on Schedule 3.2.3 were not issued in violation of any purchase option, call option, right of first refusal, preemptive right, subscription right or any similar right under any Applicable Law, any provision of the articles of association, or any Contract to which Parent is a party or by which it is otherwise bound. No Person has any right (whether contingent or otherwise) to require the Parent: (a) to allot or grant rights to subscribe for any shares; or (b) to convert any existing securities into shares or issue securities that have rights to convert into shares. Except for the Parent Shareholder Agreement and articles of association, the Parent is not a party to any shareholder, member, investor or similar agreements or understandings with respect to the repurchase or transfer of any issued share capital of the Parent. The Parent Shares shall, at the Effective Time, be validly authorized and allotted, free of Encumbrances (other than such Encumbrances incurred pursuant to the Parent Shareholder Agreement or the articles of association).
- 3.2.4 <u>Power and Authority</u>. The Parent has the power and authority to execute and deliver this Agreement and the Ancillary Agreements to which it is or will be a party and to perform its obligations hereunder and thereunder. This Agreement and the Ancillary Agreements to which it is or will be a party have been duly executed and delivered by the Parent, and constitute the legal, valid and binding obligations of the Parent, enforceable against it in accordance with their terms except as such enforceability may be limited by bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' rights generally and by general principles of equity.
- 3.2.5 Non-Contravention. The execution, delivery and performance by the Parent of this Agreement and the Ancillary Agreements to which it is or will be a party and the consummation of the transactions contemplated by this Agreement and the Ancillary Agreements to which it is or will be a party do not: (a) violate, conflict with, result in any material breach of, or constitute a default (or an event that, with notice or lapse of time or both, would constitute a default) under (i) any material Contract to which the Parent is a party, other than such consents, approvals or notices which have already been obtained or given; (ii) result in the creation of any Encumbrance on any of the Parent Shares other than as set forth in the Parent Shareholder Agreement and articles of association; (iii) the provisions of its articles of association or other

governing documents; or (iv) any order, writ, injunction or decree of any Governmental Authority entered against it or by which any of its property is bound that would adversely affect the Parent's ability to consummate the transactions contemplated by this Agreement and the Ancillary Agreements to which it is or will be a party; or (b) violate any Applicable Laws. Except for the filing of a Form SH01 in respect of the Parent Shares with the U.K. Companies House, there is no consent, approval, order or authorization of or from, or registration, notification, declaration or filing to or with, any Governmental Authority that is required by the Parent in connection with the execution, delivery or performance by the Parent of this Agreement and the Ancillary Agreements to which it is or will be a party or the consummation of the transactions contemplated hereby and thereby.

- 3.2.6 <u>Litigation</u>. There is no litigation or proceeding (including, but not limited to arbitration), in law or in equity, and there are no proceedings or governmental investigations before any commission or other administrative authority or Governmental Authority, pending, or, to the Parent's Knowledge, threatened, against the Parent or with respect to this Agreement or the consummation of the transactions contemplated hereby.
- 3.2.7 <u>Brokers</u>. No broker, investment banker, agent, finder or other intermediary acting on behalf of the Parent or under the authority thereof, is or will be entitled to any broker's or finder's fee or any other commission or similar fee directly or indirectly in connection with the transactions contemplated under this Agreement.
- 3.2.8 <u>Compliance with Applicable Laws</u>. Parent is, and has been since its formation, in compliance with all Applicable Laws in all material respects.
- 3.2.9 <u>Parent Financial Statements</u>. Parent has delivered to Sellers an unaudited balance sheet of Parent as at September 30, 2015 (the "<u>Parent Unaudited Balance Sheet</u>") and related unaudited statements of operations and cash flows, as applicable, for the period from April 24, 2015 through September 30, 2015 (the "<u>Parent Unaudited Income Statement</u>" and, together with the Parent Unaudited Balance Sheet, the "<u>Parent Financial Statements</u>"). A true copy of the Parent Financial Statements is attached at <u>Schedule 3.2.9</u>. Except as described in <u>Schedule 3.2.9</u>, the Financial Statements (a) were prepared in accordance with U.K. GAAP, consistently applied with past practice (except for the absence of footnote disclosure and any year-end audit adjustments), and (b) fairly present, in all material respects, the financial position and results of operations, and cash flows of the Parent, on a consolidated basis, as of the date and for the period indicated.
- 3.2.10 <u>Absence of Undisclosed Liabilities</u>. The Parent does not have any debt or liabilities required to be shown on a balance sheet prepared in accordance with U.K. GAAP, applied in a manner consistent with the preparation of the Parent Unaudited Balance Sheet as at September 30, 2015 except: (a) to the extent disclosed or reserved against in the Parent Unaudited Balance Sheet, or (b) for liabilities and obligations that were incurred after the date of the Parent Unaudited Balance Sheet in the ordinary course of the Business consistent in amount and kind with past practice and not individually or in the aggregate material to the Parent.
- 3.3 **Representations and Warranties of the Company**. The Company hereby represents and warrants to Merger Sub and the Parent that as of the Closing Date:

- 3.3.1 <u>Authorization</u>. The execution, delivery and performance of this Agreement and the Ancillary Agreements to which it is or will be a party have been duly authorized by the Board of Directors and stockholders of the Company. No other action or approval on the part of the Company or its Affiliates is required for the execution, delivery and performance of this Agreement by the Company.
- 3.3.2 <u>Organization</u>. The Company is a corporation duly incorporated and organized, validly existing and in good standing under the laws of the State of Delaware. The Company has all requisite power and authority to own, lease and operate the properties and assets it currently owns, leases and operates and to carry on its business and is duly qualified to transact business and is in good standing in each jurisdiction wherein the nature of the business conducted by the Company as of the Closing Date or the ownership of its assets makes such qualification necessary. The Company has previously made available to the Parent true, correct and complete copies of the certificate of incorporation, bylaws and any other governing documents of the Company.

### 3.3.3 Capitalization; Subsidiaries.

- (a) The authorized and issued and outstanding shares of capital stock of the Company are as set forth on Schedule 3.3.3(a). The Company Shares constitute all of the issued and outstanding shares of capital stock of the Company. The Company Shares have been duly authorized, are validly issued, fully paid, and non-assessable, and are held of record and beneficially by the Sellers in the proportions as set forth on Schedule 3.3.3(a), in each case, free and clear of all Encumbrances. The Company Shares were issued in conformity with all Applicable Laws, including federal and state securities Applicable Laws, and were not issued in violation of, and are not subject to, any purchase option, call option, right of first refusal, preemptive right, subscription right or any similar right under any Applicable Law, any provision of the certificate of incorporation, bylaws and any other governing documents of the Company or any Contract to which the Company is or was a party or by which it is or was otherwise bound. Except as set forth on Schedule 3.3.3(a), there are no outstanding or authorized (i) options, warrants, purchase rights, subscription rights, conversion rights, exchange rights, or other contracts or commitments that could require the Company to issue, sell, or otherwise cause to become outstanding any of the Company's capital stock, or (ii) stock appreciation, phantom stock, profit participation, or similar rights with respect to the Company. The Company does not maintain any share option plan or any other plan or agreement providing for equity compensation to any Person. Neither the Company nor any Seller is a party to any voting trusts, proxies, or other shareholder, member, investor or similar agreements or understandings with respect to the voting, repurchase, or transfer of shares of the capital stock of the Company.
- (b) The Company has no, and has never had, Subsidiaries and does not have, and has never had, any interest in, or obligation or right to acquire, purchase or subscribe for, directly or indirectly, any outstanding capital stock of, or other equity interests in, any Person.
- 3.3.4 <u>Power and Authority</u>. The Company has the power and authority to execute and deliver this Agreement and the Ancillary Agreements to which it is or will be a party and to perform its obligations hereunder and thereunder. This Agreement and the Ancillary Agreements have been duly executed and delivered by the Company, and constitute the legal, valid and binding

obligations of the Company, enforceable against it in accordance with their terms except as such enforceability may be limited by bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' rights generally and by general principles of equity.

3.3.5 Non-Contravention. The execution, delivery and performance of this Agreement by the Company and the Ancillary Agreements to which it is or will be a party and the consummation of the transactions contemplated by this Agreement and the Ancillary Agreements to which it is or will be a party do not: (a) violate, conflict with, result in any material breach of, or constitute a default (or an event that, with notice or lapse of time or both, would constitute a default) under any Contract of the Company, including the License Agreement; (b) result in the creation of any Encumbrance on any of the Company Shares; (c) violate any Applicable Laws; or (d) give any party to any Contract to which the Company is a party, including the License Agreement, the right to terminate, modify or accelerate any rights, obligations or performance under such Contract. Except for the filing of the Certificate of Merger, there is no consent, approval, order and authorization of or from, and registration, notification, declaration or filing to or with, any Person, including any Governmental Authority that is required by the Company in connection with the execution, delivery or performance by the Company of this Agreement and the Ancillary Agreements to which it is or will be a party or the consummation of the transactions contemplated hereby and thereby.

3.3.6 <u>Title to Assets</u>. The Company has the sole and exclusive right, title and interest in and to, or a valid lease or license to, all of its assets used or usable in the conduct of its business as conducted as of the Closing Date ("**Company Assets**") free and clear of all Encumbrances. Except as set forth in the License Agreement, no portion of the Company Assets has been licensed from or to any Third Party. The license grants under the License Agreement comprise all of the assets and rights that are used or held for use by the Company prior to the Closing.

### 3.3.7 Intellectual Property.

(a) Except as described on Schedule 3.3.7(a), the Company owns exclusively all right, title and interest in and to, or has valid and enforceable exclusive license rights to all of the Licensed Patent Rights and valid and enforceable non-exclusive license rights to all of the Licensed Know-How ("Company Intellectual Property Rights"). The Company Intellectual Property Rights are the only Intellectual Property Rights Controlled by the Company. The Licensed Patent Rights were developed with federal funding from the U.S. government. The Company has made available true and complete copies of all Patent Files in its possession to the Parent. Neither the Company nor any of its Affiliates Controls or otherwise uses any trademarks, trademark registrations, trademark applications, service marks, service mark registrations or service mark applications. Other than the Licensed Know-How included in the Company Intellectual Property Rights, there is no know-how, techniques, processes, methods, formulations, specifications, chemical materials, biologic materials, assays, marketing plans and strategies, software (including source code and related documentation) or other data and information (and all copyrights, trademarks, trade secret rights and other Intellectual Property Rights relating to any of the foregoing) Controlled by the Company in written, electronic or any other form.

- (b) Other than the License Agreement, there are no license agreements in respect of any of Company Intellectual Property Rights either licensed by the Company as licensor to Third Parties or any of its Affiliates or licensed from Third Parties or any of its Affiliates to the Company as licensee. The License Agreement is in full force and effect, all payments through the Closing Date required to be made thereunder by the Company have been made, and the Company is in compliance in all material respects with its respective obligations thereunder.
- (c) (i) To the Company's Knowledge, there are no facts that should reasonably support a finding of invalidity or infringement with respect to the Company Intellectual Property Rights, (ii) to the Company's Knowledge, no actions or omissions have occurred in connection with the pending patent applications comprising the Patent Rights which would reasonably be likely to render any Licensed Patent Rights unenforceable, and (iii) none of such Company Intellectual Property Rights has been or is the subject of any pending proceeding (including, with respect to the Licensed Patent Rights, inventorship challenges, interferences, reissues, reexaminations and oppositions or similar proceedings) or any order or other agreement restricting or any order or other agreement (other than the License Agreement) restricting (1) the use of any such Company Intellectual Property Rights or (2) the assignment or license thereof by the Company (or any of its Affiliates, as applicable).
- (d) Other than the License Agreement, there are no Contracts to which the Company or any of its Affiliates is a party that include royalty, license fee and other similar payment obligations of the Company (or any of its Affiliates) with respect to the Licensed Patent Rights or otherwise in connection with the exploitation of the Company Patents Rights.
- (e) To the Company's Knowledge, there is no unauthorized use, infringement, misappropriation or violation of any of the Company Intellectual Property Rights by any Person. To the Company's Knowledge, the exploitation (including the manufacture, use, sale, offer for sale or importation thereof) of the Company Intellectual Property Rights, including the Licensed Patent Rights, in the Territory does not and will not infringe or misappropriate or otherwise violate, as applicable, the Intellectual Property Rights of any Person. The Company has not received any written notice from any Person regarding, and has no Knowledge of, any claim or assertion of, any infringement, misappropriation or violation with respect to Intellectual Property Rights of any Person in connection with any of the Company Intellectual Property Rights, including the Licensed Patent Rights.
- (f) To the Company's Knowledge, all issuance, renewal, maintenance and other payments that are or have become finally due with respect to the Company Intellectual Property Rights, including the Licensed Patent Rights, have been paid by or on behalf of the Company as of the Effective Date. To the Company's Knowledge, all documents, certificates and other material in connection with the Company Intellectual Property Rights, including the Licensed Patent Rights, have, for the purposes of maintaining such Company Intellectual Property Rights, been filed in a timely manner with the relevant Governmental Authorities. The Company and to the Company's Knowledge, its Affiliates or its licensors, as applicable, have filed, prosecuted and maintained all Licensed Patent Rights and have filed, maintained or otherwise protected all other Company Intellectual Property Rights.

- (g) The Company has taken reasonable measures to maintain in confidence all Company trade secrets and Company Confidential Information.
- 3.3.8 <u>Product Sales; Inventory</u>. The Company has not developed, manufactured or Commercialized any Products in the Territory. Neither the Company or its Affiliates, nor any Third Party on behalf of The Company or its Affiliates, owns, possesses and/or is control of any inventory of finished Product for sale or use in the Territory.
  - 3.3.9 Company Compliance with Legal Requirements; Regulatory Matters.
- (a) The Company is, and has been since its formation, in compliance with all Applicable Laws in all material respects. The Company has not received any written notice of any asserted violation of Applicable Laws. The Company is not aware of any pending investigation of any Governmental Authority.
- (b) The Company possesses all Registrations from Governmental Authorities, or required by Governmental Authorities to be obtained, in each case, necessary for the lawful conduct of its business as now conducted. All such Registrations are in full force and effect in all material respects and the Company has filed all reports, notifications and filings with, and have paid all regulatory fees to, the applicable Governmental Authority necessary to maintain all of such Registrations in full force and effect. The Company is in compliance in all material respects with the terms of all such Registrations. The Company has not received written notice to the effect that a Governmental Authority was considering the amendment, termination, revocation or cancellation of any Registration. The consummation of the transactions contemplated under this Agreement, in and of itself, will not cause the revocation or cancellation of any Registration.
- (c) The Company is not a party to any corporate integrity agreements, monitoring agreements, consent decrees, settlement orders or similar agreements with or imposed by any Governmental Authority. The Company has not been placed under or otherwise made subject to the FDA's Application Integrity Policy pursuant to FDA's Compliance Policy Guide (CPG) 7150.09, 56 FR 46191 (September 10, 1991).
- (d) Neither the Company nor any of its current officers or agents, nor, to the Knowledge of the Company, any of its Affiliates, have ever been, are currently, or are the subject of a proceeding that could lead to the Company, any Seller or such employees or agents becoming, as applicable, a Debarred Entity or Debarred Individual, an Excluded Entity or Excluded Individual or a Convicted Entity or Convicted Individual. For purposes of this provision, the following definitions shall apply: (i) a "Debarred Individual" is an individual who has been debarred by the FDA pursuant to 21 U.S.C. §335a(a) or barred from providing services in any capacity to a person that has an approved or pending drug or injectable product application; (ii) a "Debarred Entity" is a corporation, partnership or association that has been debarred by the FDA pursuant to 21 U.S.C. §335a(a) or barred from submitting or assisting in the submission of any abbreviated drug application, or a subsidiary or affiliate of a Debarred Entity; (iii) an "Excluded Individual" or "Excluded Entity" is (A) an individual or entity, as applicable, who has been excluded, debarred, suspended or is otherwise ineligible to participate in federal health care programs such as Medicare or Medicaid by the Office of the Inspector General (OIG/HHS) of the U.S. Department of Health and Human Services, or (B) is an individual or entity, as applicable, who has been excluded, debarred, suspended or is otherwise ineligible to participate in federal

procurement and non-procurement programs, including those produced by the U.S. General Services Administration (GSA); and (iv) a "Convicted Individual" or "Convicted Entity" is an individual or entity, as applicable, who has been convicted of a criminal offense that falls within the ambit of 21 U.S.C. §335a(a) or 42 U.S.C. §1320a—7(a), but has not yet been excluded, debarred, suspended or otherwise declared ineligible, and in each case any foreign equivalents thereof, as applicable.

- (e) Neither the Company nor any of its current officers, employees or agents, nor, to the Knowledge of the Company, any of its Affiliates, has made an untrue statement of a material fact or fraudulent statement to any Pharmaceutical Product Regulatory Authority, failed to disclose a material fact required to be disclosed to any Pharmaceutical Product Regulatory Authority, or committed any act, made any statement, or failed to make any statement, that would reasonably be expected to provide a basis for the FDA to invoke its policy respecting "Fraud, Untrue Statements of Material Fact, Bribery, and Illegal Gratuities", set forth in 56 Fed. Reg. 46191 (September 10, 1991) or any similar Applicable Law in any other country in the Territory.
- (f) The Company has no Knowledge of any scientific or technical fact or circumstance that would reasonably be expected to materially and adversely affect the scientific, therapeutic or commercial viability of the Licensed Patent Rights or any Product, including the ability to obtain a Registration for any Product.
- (g) The Company has not been notified in writing by any Third Party or any Governmental Authority of any material failure (or any material investigation with respect thereto) by them or any licensor, licensee, partner or distributor to comply with, or maintain systems and programs to ensure compliance with, any Applicable Laws.
- (h) All personal data collected, processed and disclosed by the Company or any of its Affiliates, including any information or data collected during any clinical trials conducted during the development, Preclinical Studies and clinical testing, manufacture, storage, distribution, supply and administration of the Licensed Patent Rights or any Product, have been, and are being, collected, processed, transferred, stored, used and disclosed in material compliance with (A) all Applicable Laws and industry standards, including the Health Insurance Portability and Accountability Act of 1996 and the implementing regulations of the U.S. Department of Health and Human Services, Directive 95/46/EC of 24 October 1995 and the implementing laws of the individual European Union countries and (B) the Company's privacy, data protection and information security policies and practices (collectively "Privacy Practices"). Neither the Company nor any of its Affiliates have received any: (i) written notice or complaint alleging non-compliance with any Applicable Laws or the Privacy Practices relating to the collection, processing and disclosure of information or data; (ii) written claim for compensation for loss or unauthorized collection, processing or disclosure of data; or (iii) written notification of an application for rectification, erasure or destruction of information or data that is still outstanding.
- (i) No claims have been asserted nor, to the Company's Knowledge, are threatened against the Company or its Affiliates by any person, regulator, law enforcement agency or entity alleging a violation of any privacy, personal or confidentiality rights under any of the Privacy Practices or Applicable Laws. With respect to all personal or user information collected

by the Company, the Company has at all times taken all commercially reasonable steps necessary (including, without limitation, implementing and monitoring compliance with reasonable measures with respect to administrative safeguards and technical and physical security) to (i) protect such information against loss and against unauthorized access, use, modification, disclosure or other misuse and (ii) comply with Applicable Law and the Privacy Practices in its collection, processing, storage, use, disclosure and transfer of such information.

To the Knowledge of the Company, there has been no unauthorized access to, theft, breach or disclosure of or other misuse of that information. To the Knowledge of the Company, there has been no unauthorized disclosure, whether pursuant to Applicable Law or the Privacy Practices, of electronic communications, patient data, clinical data or protected health information to any Third Party, including any Governmental Authority.

- (j) The Company has made available to the Parent (i) complete and correct copies of the Registrations, including all supplements and amendments thereto, (ii) all correspondence sent to and received from any Governmental Authority or any Institutional Review Board, and (iii) all existing written records relating to all discussions and meetings between or involving the Company and any Governmental Authority or Institutional Review Board.
- (k) The Company has made available, or has caused its Affiliates to make available, to the Parent all Technical Information and Regulatory Documentation, and any other data, clinical studies and Preclinical Studies in the Company's or the Company's Affiliates' Control, and all such Technical Information and Regulatory Documentation were and are true, complete and correct at such time and as of the date hereof. The Company has prepared, maintained and retained all Regulatory Documentation that is required to be maintained or reported pursuant to and, to the extent applicable, in accordance with Applicable Laws and, to the Knowledge of the Company, all such information is true, complete and correct in what it purports to be.
- (l) The Company is not now, and has never have been, party to a Government Contract. Neither the Company nor any of its Subsidiaries are now, and have never been, a Contractor or Subcontractor as those terms are defined and used in the U.S. federal procurement law and regulation, including but not limited to the Federal Acquisition Regulation ("FAR") and the U.S. Department of Defense Supplement to the FAR ("DFAR").
- (m) No "bad actor" disqualifying event described in Rule 506(d)(1)(i)- (viii) of the Securities Act (a "**Disqualification Event**") is applicable to the Company or, to the Company's knowledge, any Covered Person (as defined in this <u>Section 3.3.9(m</u>)), except for a Disqualification Event as to which Rule 506(d)(2)(ii-iv) or (d)(3) of the Securities Act is applicable. "**Covered Person**" means, with respect to the Company or Parent as an "issuer" for purposes of Rule 506 promulgated under the Securities Act, any person listed in the first paragraph of Rule 506(d)(1) of the Securities Act.
  - (n) The Company is not required to register as an "investment company" under the Investment Company Act of 1940.
- 3.3.10 <u>Litigation</u>. There is no litigation or proceeding (including, but not limited to arbitration), in law or in equity, and there are no proceedings or governmental investigations before any commission or other administrative authority or Governmental Authority, pending, or, to the Company's Knowledge, threatened, against the Company or with respect to the consummation of the transactions contemplated hereby.

3.3.11 Contracts. The License Agreement and Investment Agreements comprise all of the Contracts between the Company or its Affiliates and Third Parties pursuant to which the Company has rights and/or obligations (the "Company Contracts"). The Company has made available to the Parent a true and correct copy of the Company Contracts. The Company Contracts are in full force and effect and constitute valid and binding obligations of the Company and, to the Knowledge of the Company, the other parties thereto. Neither the Company nor, to the Knowledge of the Company, the other parties to the Company Contracts are in default thereunder, and the Company has not received or given notice of any default thereunder from or to any of the other parties thereto, and, to the Knowledge of the Company, there exists no event which upon notice or the passage of time, or both, would reasonably be expected to give rise to any default by the Company or the other parties thereto. The Company has not received any written notice, nor does the Company have any Knowledge that any party to any Company Contract intends to cancel or terminate any Company Contract.

# 3.3.12 Employee Matters.

- (a) The Company does not have, and has never had, any employees.
- (b) The Company does not maintain, sponsor, or contribute to, has never maintained, sponsored or contributed to (and is not, and has never been, required to contribute to) any Employee Benefit Plan, and the Company has no liability and has never had any liability (joint, several, contingent or otherwise) with respect to any Employee Benefit Plan maintained, operated or otherwise contributed to by Seller or an ERISA Affiliate from and after the Closing.
  - (c) The Company is not a party to nor has any Contract with any independent contractor, consultant or advisor.
- 3.3.13 <u>Brokers</u>. No broker, investment banker, agent, finder or other intermediary acting on behalf of the Company or under the authority thereof, is or will be entitled to any broker's or finder's fee or any other commission or similar fee directly or indirectly in connection with the transactions contemplated under this Agreement.

# 3.3.14 Taxes.

- (a) All U.S. federal, state, local, and non-U.S. Tax Returns relating to any and all Taxes concerning or attributable to the Company, have been timely filed, and such Tax Returns are true and correct in all material respects and have been completed in accordance with applicable law in all material respects. The Company has provided to the Parent copies of all Tax Returns filed by or on behalf of the Company since its incorporation on July 11, 2012. The Company was not required in accordance with applicable law to file any Tax returns in respect of the years ended December 31, 2012 and 2013.
- (b) All Taxes (whether or not shown on any Tax Return) required to be paid by or on behalf of the Company have been timely paid. There are no Encumbrances for Taxes upon the Company or any of its assets. There is no reasonable basis for the assertion of any claim relating or attributable to Taxes which, if adversely determined, would result in any Encumbrances for Taxes on the Company or any of its assets.

- (c) There is no Tax deficiency outstanding, assessed, or proposed against or with respect to the Company or any of its assets, nor has there been executed or requested any outstanding waiver of any statute of limitations on or extension of the period for the assessment or collection of any Tax of or with respect to the Company or any of its assets.
- (d) Neither the Company nor any of its Affiliates has been notified of any request for an audit, examination, or proceeding with respect to any Tax Return that relates to or concerns the Company, nor is any such audit, examination, or proceeding presently in progress. No adjustment relating to any Tax Return filed by or with respect to the Company has been proposed by any Taxing Authority. No claim has ever been made that the Company is or may be subject to taxation in a jurisdiction in which it does not file Tax Returns.
  - (e) None of the Company Shares is a "United States real property interest" within the meaning of Section 897(c)(1) of the Code.
- 3.3.15 <u>Real Property</u>. The Company (i) does not own or lease any real property and (ii) has not (nor has any predecessor thereof) owned or leased in the past any real property.
  - 3.3.16 Financial Statements; Indebtedness; No Material Adverse Effect.
- (a) Attached to Schedule 3.3.16(a) is the Tax Return of the Company on Form 1120 containing an unaudited balance sheet of the Company as of December 31, 2014. Other than as attached to Schedule 3.3.16(a), the Company has not prepared any other financial statements of the Company as of or for the periods ended December 31, 2014 or as of any date, or for any period ended, after December 31, 2014. The unaudited balance sheet of the Company as of December 31, 2014 attached to Schedule 3.3.16(a) is accurate in all material respects, is consistent, in all material respects, with the books and records of the Company, has been prepared in accordance with U.S. GAAP, and presents fairly, in all material respects, the financial condition of the Company as of December 31, 2014. Since December 31, 2014, the Company's assets and liabilities as would be reflected on an unaudited balance sheet of the Company as of the Closing Date prepared in accordance with U.S. GAAP have not changed. Schedule 3.3.16(a) sets forth the Company's historical expenditures, if any, since its incorporation on July 11, 2012 on a quarterly basis (or if no such expenditures have been so incurred, so states).
- (b) The Company (i) has no (A) indebtedness for borrowed money or other interest-bearing indebtedness owed under any under credit agreement or facility, (B) indebtedness evidenced by any note, bond, debenture or other debt security or instrument, (C) indebtedness secured by a security interest, pledge or mortgage on its assets, indebtedness for the deferred purchase price of property or services with respect to which it is liable, contingently or otherwise, as obligor or otherwise, (D) capitalized lease obligations, synthetic lease obligations and sale leaseback obligations, whether secured or unsecured, or (E) obligations under interest rate cap, swap, collar or similar transactions or currency hedging transactions; (ii) is not party to any letters of credit, performance bonds or bankers acceptances; and (iii) has not guaranteed, directly or indirectly, in any manner any indebtedness of any type described in the foregoing clauses (i) and (ii) of any other Person. All indebtedness of any type described in the foregoing sentence has been paid or otherwise discharged in full at or prior to the Closing.

- (c) Since January 31, 2015, no Material Adverse Effect has occurred or is continuing.
- 3.3.17 <u>Interested Party Transactions</u>. None of the Sellers or their respective Affiliates or Affiliates of the Company (collectively, the "**Interested Parties**") (a) except for (i) the License Agreement to which Brandeis is a party, and (ii) the Investment Agreements to which each Seller is a party, is presently a party to any Contract or other arrangement with the Company, or (b) except for the Licensed Patent Rights owned by Brandeis and licensed to the Company under the License Agreement, owns any interest in any assets used by the Company. There are no outstanding Liabilities, notes payable from or advances by the Company to, and the Company is not otherwise a creditor of, an Interested Party, each of which Liabilities, notes payable, receivables or advances shall be paid or otherwise discharged in full at or prior to the Closing.
- 3.3.18 Environmental Matters. The Company has complied in all material respects with all Applicable Laws intended to protect the environment and/or human health or safety (collectively, "Environmental Laws"). The Company has not released, handled, generated, used, stored, transported or disposed of any material, substance or waste which is regulated by Environmental Laws ("Hazardous Materials"). The Company has no Knowledge of any environmental investigation, study, test or analysis, the purpose of which was to discovery, identify, or otherwise characterize the condition of the soil, groundwater, air or the presence of Hazardous Materials at any location at which the business of the Company has been conducted. The Company does not have Environmental Liabilities that would reasonably be expected to have a Material Adverse Effect. As used herein, "Environmental Liabilities" are any claims, demands, or liabilities under Environmental Law which arise out of or in any way relate to the operations or activities of the Company, or any real property at any time owned, operated or leased by the Company, whether contingent or fixed, actual or potential, and arise from or relate to actions occurring (including any failure to act) or conditions existing on or before the Closing Date.
- 3.3.19 <u>Undisclosed Liabilities</u>. The Company does not have any Liability (whether known or unknown, whether absolute or contingent, whether liquidated or unliquidated and whether due or to become due), except for contractual liabilities incurred in the ordinary course of business under the Company Contracts.
- 3.3.20 <u>Full Disclosure</u>. None of the representations or warranties made by the Company in this Agreement or any Ancillary Agreement to which it is or will be a party, nor statements made in the Company and Seller Disclosure Schedules or any certificate furnished by the Company pursuant to this Agreement or any Ancillary Agreement to which it is or will be a party, when taken together, contain any untrue statement of a material fact, or omits to state any material fact necessary in order to make the statements contained herein or therein, in the light of the circumstances under which they were made, not misleading.

- 3.4 **Representations and Warranties of the Sellers**. Except with respect to the representations and warranties contained below in <u>Section 3.4.7</u> as to which Brandeis makes no such representations and warranties, each Seller, severally as to such Seller, hereby represents and warrants to Merger Sub and the Parent that as of the Closing Date:
- 3.4.1 <u>Authorization</u>. The execution, delivery and performance of this Agreement and the Ancillary Agreements to which it is or will be a party have been duly authorized by such Seller or, if applicable, the board of directors or similar governing body of such Seller. No other action or approval on the part of such Seller is required for the execution, delivery and performance of this Agreement by such Seller and the Ancillary Agreements to which it is or will be a party.
- 3.4.2 <u>Organization</u>. Such Seller, if such Seller is an entity, is validly existing and in good standing under the laws of the state of its organization and has the requisite power and authority necessary to enter into, deliver and perform its obligations pursuant to each of the Transaction Documents to which it is or will be a party. Such Seller, if such Seller is an individual, has all necessary legal capacity to enter into each of the Transaction Documents to which it is or will be a party and to perform all of his or her obligations pursuant to each of the Transaction Documents to which such Seller is or will be a party.
- 3.4.3 <u>Title to Company Shares</u>. Such Seller (a) is the sole record and beneficial owner of, the Company Shares set forth opposite such Seller's name on <u>Schedule 3.3.3(a)</u>; (b) except as set forth in the Investment Agreements, is not a party to any voting trust, proxy or other agreement or understanding with respect to the voting of such Company Shares; (c) except as set forth in the Investment Agreements, is not a party to any option, warrant, purchase right or other Contract that could require such Seller to sell, transfer or otherwise dispose of any of such Seller's Company Shares (other than this Agreement); (d) has full power, right and authority, and any approval required by Applicable Laws, to make and enter into this Agreement; and (e) has good, valid and marketable title to such Seller's Company Shares set forth opposite such Seller's name on <u>Schedule 3.3.3(a)</u>, free and clear of all Encumbrances. Upon consummation of the transactions contemplated by this Agreement, and, assuming that the other Seller's party to this Agreement have good and marketable title to such Seller's Company Shares set forth opposite such Seller's name on <u>Schedule 3.3.3(a)</u>, free and clear of all Encumbrances, the Parent will acquire good and marketable title to 100% of the capital stock of the Company, free and clear of all Encumbrances. Such Seller has consented to the Merger in accordance with Section 228 of Delaware Law and/or by conduct by tendering such Seller's Company Shares and thereby forfeits all of such Seller's appraisal rights in respect of the Merger under Section 262 of Delaware Law.
- 3.4.4 <u>Power and Authority</u>. Such Seller has the power and authority to execute and deliver this Agreement and the Ancillary Agreements to which it is or will be a party and to perform its obligations hereunder and thereunder. This Agreement and the Ancillary Agreements to which such Seller is a party have been duly executed and delivered by such Seller, and constitute the legal, valid and binding obligations of such Seller, enforceable against such Seller in accordance with their respective terms except as such enforceability may be limited by bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' rights generally and by general principles of equity.

- 3.4.5 Non-Contravention. The execution, delivery and performance by such Seller of this Agreement and the Ancillary Agreements to which it is or will be a party and its compliance with the terms and provisions hereof and thereof do not conflict with or result in a breach of any of the terms and provisions of or constitute a default under: (a) a loan agreement, guaranty, financing agreement, agreement affecting a product or other agreement or instrument binding or affecting it or its property that would adversely affect such Seller's ability to consummate the transactions contemplated by this Agreement and the Ancillary Agreements to which it is or will be a party; (b) if an entity, the provisions of such Sellers certificate or articles of incorporation, bylaws or similar governing documents; or (c) any order, writ, injunction or decree of any Governmental Authority entered against such Seller or by which any of such Seller's property is bound that would adversely affect such Seller's ability to consummate the transactions contemplated by this Agreement and the Ancillary Agreements to which such Seller is a party.
- 3.4.6 <u>Litigation</u>. There is no litigation or proceeding (including, but not limited to arbitration), in law or in equity, and there are no proceedings or governmental investigations before any commission or other administrative authority or Governmental Authority, pending, or, to such Seller's Knowledge, threatened, against such Seller with respect to this Agreement or the consummation of the transactions contemplated hereby.

# 3.4.7 Regulatory Matters.

(a) None of Fidelity, Petsko or Ringe, nor, solely with respect to Fidelity, any of Fidelity's current officers, directors or employees, nor, to the actual knowledge of Fidelity, any independent contractor or agent of Fidelity involved in preparing or submitting any Regulatory Documentation, has ever been, is currently, or is the subject of a proceeding that could lead to the Company, such Seller or any such employees or agents becoming, as applicable, a Debarred Entity or Debarred Individual, an Excluded Entity or Excluded Individual or a Convicted Entity or Convicted Individual. For purposes of this provision, the following definitions shall apply: (i) a "Debarred Individual" is an individual who has been debarred by the FDA pursuant to 21 U.S.C. §335a(a) or barred from providing services in any capacity to a person that has an approved or pending drug or injectable product application; (ii) a "Debarred Entity" is a corporation, partnership or association that has been debarred by the FDA pursuant to 21 U.S.C. §335a(a) or barred from submitting or assisting in the submission of any abbreviated drug application, or a subsidiary or affiliate of a Debarred Entity; (iii) an "Excluded Individual" or "Excluded Entity" is (A) an individual or entity, as applicable, who has been excluded, debarred, suspended or is otherwise ineligible to participate in federal health care programs such as Medicare or Medicaid by the Office of the Inspector General (OIG/HHS) of the U.S. Department of Health and Human Services, or (B) is an individual or entity, as applicable, who has been excluded, debarred, suspended or is otherwise ineligible to participate in federal procurement and non-procurement programs, including those produced by the U.S. General Services Administration (GSA); and (iv) a "Convicted Individual" or "Convicted Entity" is an individual or entity, as applicable, who has been convicted of a criminal offense that falls within the ambit of 21 U.S.C. §335a(a) or 42 U.S.C. §1320a—7(a), but has not yet been excluded, de

- (b) None of Fidelity, Petsko or Ringe, nor, solely with respect to Fidelity, any of Fidelity's current officers, directors or employees, nor, to the actual knowledge of Fidelity, any independent contractor or agent of Fidelity involved in preparing or submitting any Regulatory Documentation, has made an untrue statement of a material fact or fraudulent statement to any Pharmaceutical Product Regulatory Authority, failed to disclose a material fact required to be disclosed to any Pharmaceutical Product Regulatory Authority, or committed any act, made any statement, or failed to make any statement, that would reasonably be expected to provide a basis for the FDA to invoke its policy respecting "Fraud, Untrue Statements of Material Fact, Bribery, and Illegal Gratuities", set forth in 56 Fed. Reg. 46191 (September 10, 1991) or any similar Applicable Law in any other country in the Territory.
- 3.4.8 <u>Brokers</u>. No broker, investment banker, agent, finder or other intermediary acting on behalf of such Seller or under the authority thereof, is or will be entitled to any broker's or finder's fee or any other commission or similar fee directly or indirectly in connection with the transactions contemplated under this Agreement.

# 3.4.9 Investor Representations.

- (a) Such Seller is an "accredited investor" as such term is defined in Rule 501(a) of Regulation D under the United States Securities Act of 1933, as amended (the "Securities Act"), and has such knowledge and experience in financial and business matters that such Seller is capable of evaluating the merits and risks of the investment in such Seller's portion of the Parent Shares. Such Seller believes he or it has received all the information regarding Parent and Merger Sub that he or it considers necessary or appropriate for deciding whether to acquire such Seller's portion of the Parent Shares.
- (b) Such Seller is acquiring such Seller's portion of the Parent Shares solely for such Seller's own account (not as a nominee or agent) for investment purposes and does not have any Contract with any person to sell, transfer or grant participations to any third person with respect to any portion of the Parent Shares for such Seller.
- (c) The Parent has made available to such Seller all material that has been requested by such Seller and has provided answers to all questions of such Seller regarding the terms and conditions of the offering of the Parent Shares and the business, properties, prospects, and financial condition of the Parent and its Subsidiaries, including Merger Sub, and such additional information (to the extent the Parent possessed such information or could acquire it without unreasonable effort or expense) necessary to verify the accuracy of any information furnished or made available to such Seller by the Parent. Such Seller has had an opportunity to inspect such books and records and material contracts as such Seller deemed necessary to its determination to acquire such Seller's portion of the Parent Shares. Such Seller believes he or it has received all the information it considers necessary or appropriate for deciding whether to purchase the Parent Shares.
- (d) Such Seller understands that an investment in the Parent Shares is highly speculative and that there can be no assurance as to what return, if any, there may be. Such Seller further understands that no public market now exists for all or any portion of the shares comprising the Parent Shares, that there can be no assurance that a public market will ever exist for the shares comprising the Parent Shares and that the Parent is under no obligation to register

any portion of the Parent Shares for such Seller. Such Seller (i) has no need for liquidity in its investment in such Seller's portion of the Parent Shares, (ii) is able to bear the substantial economic risks of an investment in such Seller's portion of the Parent Shares for an indefinite period, and (iii) at the present time, can afford a complete loss of such investment in such Seller's portion of the Parent Shares. If an individual, such Seller's current commitments to illiquid investments is not disproportionate to such Seller's net worth and such Seller's investment in such Seller's portion of the Parent Shares will not cause such commitment to become disproportionate. Such Seller acknowledges that no federal, state or other governmental agency has made any findings or determination as to the fairness of the offering for investment, nor any recommendation or endorsement of the Parent Shares. The offering of the Parent Shares has not been reviewed for accuracy or completeness by any federal, state or other securities commissioner or agency.

- (e) Such Seller was not offered or sold the Parent Shares, directly or indirectly, by means of any form of general solicitation or general advertisement, including (i) any advertisement, article, notice or other communication published in any newspaper, magazine or similar medium or broadcast over television or radio or (ii) any seminar or other meeting whose attendees had been invited by general solicitation or general advertising.
- (f) Such Seller acknowledges and understands that the Parent Shares have not been registered under the Securities Act or any other securities laws by reason of a specific exemption thereunder, and that any certificates evidencing such Seller's portion of the Parent Shares will be imprinted with legends restricting their transfer other than in compliance with the Securities Act and other applicable securities laws. Such Seller acknowledges that such Seller's portion of the Parent Shares must be held indefinitely unless subsequently registered under the Securities Act or the Parent receives an opinion of counsel satisfactory to the Parent that such registration is not required.
- (g) Such Seller understands that the Parent Shares have not been registered under the Securities Act on the ground that the sale provided for in this Agreement and the issuance of securities hereunder is exempt from registration under the Securities Act pursuant to Section 4(2) thereof, Regulation D or other specific exemption thereunder, and that the Company's reliance on such exemption is predicated on the accuracy of such Seller's representations set forth herein.
- (h) To the extent that such Seller is a Covered Person (as defined in Section 3.3.9(m) of this Agreement), no Disqualification Event (as defined in Section 3.3.9(m) of this Agreement) is applicable to such Seller, except for a Disqualification Event as to which Rule 506(d)(2)(ii-iv) or (d)(3) of the Securities Act is applicable.
- (i) Such Seller is a US person (as provided for by the Securities Act 1933) and acknowledges no offer of the Parent Shares has been made to such Seller in any jurisdiction other than the United States of America.
- 3.5 **Additional Representations and Warranties of Brandeis**. Brandeis hereby represents and warrants to Merger Sub and the Parent that as of the Closing Date:

- 3.5.1 <u>Validity of the License Agreement</u>. The License Agreement (a) is the legal, valid and binding license to the Licensed Patent Rights, enforceable against Brandeis in accordance with its terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' rights generally and by general principles of equity, and (b) represents the complete agreement and understanding between Brandeis and the Company relating to the Licensed Patent Rights as of the Closing Date. The License Agreement has not been amended, modified or supplemented as of the Closing Date, other than the amendment contemplated to be entered into simultaneously with the Closing pursuant to the terms of this Agreement. The License Agreement is in full force and effect, all payments through the Closing Date required to be made thereunder by the Company have been made, and the Company is in compliance in all material respects with its respective obligations thereunder.
- 3.5.2 Rights to Licensed Patent Rights. All rights, title and interest of Ringe, Petsko and Xu Simon (collectively, the "Inventors") in the Licensed Patent Rights have been assigned to Brandeis and Brandeis has delivered copies of the patent assignments to the Parent. To the Knowledge of Brandeis's Office of Technology Licensing (after inquiry with Brandeis's Office of General Counsel), Brandeis has not received any written notice from any Person claiming or asserting any infringement, misappropriation or violation with respect to Intellectual Property Rights of any Person in connection with any of the Licensed Patent Rights. To the Knowledge of Brandeis's Office of Technology Licensing (after inquiry with Brandeis's Office of General Counsel), no event has occurred or circumstance exists that (with or without notice or lapse of time) would cause or would be reasonably expected to cause Brandeis not to be able to license the Licensed Patent Rights in accordance with terms of the License Agreement, provided, however, that nothing in this sentence is intended to be (nor shall it be construed as) a representation or warranty that the use of the Company Intellectual Property Rights does not infringe the Intellectual Property Rights of another Person. All issuance, renewal, maintenance and other payments that are or have become finally due with respect to the Licensed Patent Rights have been paid as of the Closing Date. All documents, certificates and other material in connection with the Licensed Patent Rights have, for the purposes of maintaining such Licensed Patent Rights, been filed in a timely manner with the relevant Governmental Authorities. Brandeis has filed, prosecuted and maintained or caused to be filed, prosecuted and maintained on its behalf, all Licensed Patent Rights.
  - 3.5.3 <u>Use of Government Funding</u>. The Licensed Patent Rights were developed at least in part with federal funding from the U.S. government.
- 3.5.4 No Right to Additional Company Shares of Parent. Except for the portion of the Parent Shares set forth opposite Brandeis's name on Schedule 2.1.5, immediately after the consummation of the transactions contemplated by this Agreement, Brandeis is not, and will not be, entitled to, credited as fully paid, any A ordinary shares of £0.0001 in the capital of the Parent or any other ordinary shares or securities convertible into or exercisable or exchangeable for ordinary shares of Parent pursuant to the License Agreement or otherwise. Brandeis acknowledges that neither Parent nor any of its Affiliates is, nor will be, obligated to issue Brandeis any Anti-Dilution Protection Adjustment Shares (as defined in the License Agreement) pursuant to Exhibit A of the License Agreement, any other provision of the License Agreement or otherwise.

# 4. CLOSING DELIVERIES

4.1 **Deliveries of the Company and Sellers**. At the Closing, the Company and each of the Sellers shall deliver, or cause to be delivered, to the Parent the following:

- 4.1.1 <u>Ancillary Agreements</u>. The Company and each Seller shall have delivered to Merger Sub or the Parent each Ancillary Agreement listed on <u>Schedule 4.1.1</u> to which it is or will be a party, each of which shall have been validly executed by a duly authorized representative of the Company or such Seller, as applicable.
- 4.1.2 <u>Resignations</u>. The Company shall have delivered to the Parent, the resignations and releases, effective as of the Closing Date, of the officers and directors of the Company.
- 4.1.3 <u>Corporate Certificate</u>. The Company shall have delivered to the Parent a certificate dated as of the Closing Date and signed on the Company's behalf by an officer of the Company certifying as follows: (a) the Company's Certificate of Incorporation and bylaws, or equivalent organizational documents, attached to such certificate is true, correct and complete, in full force and effect in the form attached to such certificate from and after the date of the adoption of the resolutions referred to in clause (b) below, and no amendment to such Certificate of Incorporation has occurred from and after the date of the last amendment annexed thereto; (b) the resolutions of the stockholders, if applicable, and the Board of Directors of the Company attached to such certificate authorizing this Agreement, the Ancillary Agreements and the transactions contemplated by this Agreement and the Ancillary Agreements were duly adopted at a duly convened meeting thereof or by written consent, remain in full force and effect, and have not been amended, rescinded or modified; and (c) the incumbency of its directors and officers as of the Closing.
- 4.1.4 <u>FRPTA Certification</u>. The Company shall have delivered to the Parent a certificate that meets the requirements of Treasury Regulations Section 1.1445-2(c)(3) dated as of the Closing Date, certifying that the Company has not been a "United States real property holding corporation" within the meaning of Section 897(c)(2) of the Code at any time during the five year period ending on the Closing Date.
- 4.1.5 <u>Amendment to License Agreement</u>. The License Agreement shall be amended in form and substance satisfactory to the Parent in the form attached hereto as <u>Exhibit</u> C (the "**License Agreement Amendment**").
- 4.1.6 <u>Termination of the Investment Agreements</u>. The Company and the Sellers shall have delivered a termination agreement in form and substance satisfactory to Parent with respect to the termination as of the Effective Time of the Investment Agreements as set forth on <u>Schedule 4.1.1</u>.
- 4.2 **Deliveries of the Parent**. At the Closing, the Parent and Merger Sub shall deliver, or cause to be delivered, to the Sellers' Representative the following:
- 4.2.1 <u>Ancillary Agreements</u>. The Parent shall have delivered to the Sellers' Representative each Ancillary Agreement listed on <u>Schedule 4.2.1</u>, each of which shall have been validly executed by a duly authorized representative of Parent.

- 4.2.2 <u>Corporate Certificate</u>. The Parent shall deliver to the Seller's Representative a certificate dated as of the Closing Date and signed on the Parent's behalf by an authorized director or officer of the Parent certifying as follows: (a) the Parent's articles of association are true, correct and complete, in full force and effect in the form attached to such certificate from and after the date of the corporate approvals referred to in clause (b) below, and no amendment to such Certificate of Incorporation has occurred from and after the date of the last amendment annexed thereto; (b) that this Agreement, the Ancillary Agreements and the transactions contemplated by this Agreement and the Ancillary Agreements were duly authorized by all necessary corporate action and have not been amended, rescinded or modified; and (c) the incumbency of its directors and officers as of the Closing.
- 4.2.3 <u>Corporate Certificate</u>. Merger Sub shall have delivered to the Sellers' Representative a certificate dated as of the Closing Date and signed on the Company's behalf by an officer of the Company certifying as follows: (a) Merger Sub's certificate of incorporation and bylaws, or equivalent organizational documents, attached to such certificate is true, correct and complete, in full force and effect in the form attached to such certificate from and after the date of the adoption of the resolutions referred to in clause (b) below, and no amendment to such Certificate of Incorporation has occurred from and after the date of the last amendment annexed thereto; (b) the resolutions of the sole stockholder, if applicable, and the Board of Directors of Merger Sub attached to such certificate authorizing this Agreement, the Ancillary Agreements and the transactions contemplated by this Agreement and the Ancillary Agreements were duly adopted at a duly convened meeting thereof or by written consent, remain in full force and effect, and have not been amended, rescinded or modified; and (c) the incumbency of its directors and officers as of the Closing.

# 5. COVENANTS.

# 5.1 Confidentiality.

- 5.1.1 <u>Fidelity</u>. From and after the Closing, Fidelity shall, and shall cause its Affiliates to, hold, and shall use its reasonable best efforts to cause its and their respective Representatives to hold, in confidence and not use any and all Company Confidential Information, whether written or oral, concerning the Company or any Confidential Information of Parent disclosed to Fidelity.
- 5.1.2 <u>Brandeis, Petsko and Ringe</u>. From and after the Closing, each of Brandeis, Petsko and Ringe shall, and shall cause its Affiliates to, hold, and shall use its reasonable efforts to cause its and their respective Representatives to hold, in confidence, and not use, (a) any and all Company Confidential Information, whether written or oral, concerning the Company or (b) any Confidential Information of Parent disclosed to Brandeis, Petsko or Ringe, except that, with respect to Company Confidential Information, (x) Brandeis and its Affiliates and their respective Representatives shall (i) be permitted to use the subject matter described and claimed in the Patent Rights for non-commercial purposes to the extent permitted by Section 2.3 of the License Agreement (as amended by the License Agreement Amendment), (ii) retain all rights to the Licensed Know-How, except to the extent licensed under Section 2.1 of the License Agreement (as amended by the License Agreement Amendment), and (y) Petsko and Ringe shall be permitted to use (i) the Licensed Patent Rights (A) for or on behalf of the Parent or its Affiliates, or (B) for non-commercial, academic purposes in his or her capacity as a faculty member of Brandeis or other academic institution disclosed in writing to Parent, or (ii) the Licensed Know-How as permitted by Brandeis (except to the extent licensed under Section 2.1 of the License Agreement (as amended by the License Agreement Amendment)).

- 5.1.3 <u>Company Confidential Information</u>. As used herein, "**Company Confidential Information**" is Confidential Information of the Company except to the extent that such Confidential Information (a) is generally available to and known by the public through no fault of such Seller, any of its Affiliates or their respective Representatives; or (b) is lawfully acquired by such Seller, any of its Affiliates or their respective Representatives from and after the Closing from sources which are not prohibited from disclosing such information by a legal, contractual or fiduciary obligation. Solely for the purposes of applying this Section 5.1 to Brandeis and notwithstanding anything to the contrary in this Agreement, information that is or has been independently developed by Brandeis, any of its Affiliates, or any of their respective Representatives shall not constitute Company Confidential Information.
- 5.1.4 <u>Disclosure Required under Applicable Law</u>. If any Seller or any of its Affiliates or their respective Representatives are compelled to disclose any Company Confidential Information or Confidential Information of Parent by judicial or administrative process or by other requirements of Applicable Law, such Seller shall promptly notify the Parent or the Company in writing and shall disclose only that portion of such Company Confidential Information or Confidential Information of Parent, as applicable, which such Seller is advised by its counsel in writing is legally required to be disclosed, provided that such Seller, at Parent's cost, shall use reasonable best efforts to obtain (or to permit Parent to obtain) an appropriate protective order or other reasonable assurance that confidential treatment will be accorded such Company Confidential Information or Confidential Information of Parent, as applicable.
- 5.2 **Noncompetition and Nonsolicitation.** For a period commencing on the Closing Date and (x) with respect to Fidelity, ending thirty-six months following the Closing Date, and (y) with respect to Petsko and Ringe, thirty-six months following the first Registration in the United States, no Restricted Party shall, and no Restricted Party shall permit any of its Affiliates to, directly or indirectly:
- (a) Consult with, render services for or otherwise engage in any business, endeavor or activity anywhere in the Territory for the development, manufacture, use or Commercialization of any Competing Technology; provided, that, (y) Petsko and Ringe shall be permitted to use the Licensed Patent Rights and Licensed Know-How (i) for or on behalf of the Parent or its Affiliates, or (ii) for non-commercial, academic purposes in his capacity as a faculty member of Brandeis or other academic institution disclosed in writing to Parent;
- (b) Hire or solicit any employee of the Company or its Affiliates or encourage any such employee to leave such employment or hire any such employee who has left such employment; *provided*, *that* nothing in this Section 5.2 shall prevent any Restricted Party or any of its Affiliates from hiring (i) any employee whose employment has been terminated by the Company or its Affiliates or (ii) after 180 days from the date of termination of employment, any employee whose employment has been terminated by the employee; or
- (c) solicit or entice, or attempt to solicit or entice, any clients or customers of the Company or potential clients or customers of the Company for purposes of diverting their business or services from the Company.

For the avoidance of doubt, the restrictions contained in this <u>Section 5.2</u> shall not apply to Brandeis, which shall be subject in all respects to the rights and restrictions with respect to the Licensed Patent Rights and Licensed Know-How as set forth in the License Agreement (as amended).

- 5.2.2 <u>Right to Equitable Relief</u>. Each Restricted Party acknowledges that a breach or threatened breach of this <u>Section 5.2</u> would give rise to irreparable harm to the Parent and its Affiliates, for which monetary damages would not be an adequate remedy, and hereby agrees that in the event of a breach or a threatened breach by any Restricted Party of any such obligations, the Parent or its Affiliates shall, in addition to any and all other rights and remedies that may be available to it in respect of such breach, be entitled to equitable relief, including a temporary restraining order, an injunction, specific performance and any other relief that may be available from a court of competent jurisdiction (without any requirement to post bond).
- 5.2.3 Reasonableness of Restrictions. Each Restricted Party acknowledges that the restrictions applicable to such Restricted Party contained in this Section 5.2 are reasonable in duration and scope (geographic and otherwise) and necessary to protect the legitimate interests of the Parent and its Affiliates and constitute a material inducement to the Parent and Merger Sub to enter into this Agreement and consummate the transactions contemplated by this Agreement. In the event that any covenant contained in this Section 5.2 should ever be adjudicated to exceed the time, geographic, product or service, or other limitations permitted by Applicable Law in any jurisdiction, then any court is expressly empowered to reform such covenant, and such covenant shall be deemed reformed, in such jurisdiction to the maximum time, geographic, product or service, or other limitations permitted by Applicable Law. The covenants contained in this Section 5.2 and each provision hereof is severable and distinct covenants and provisions. The invalidity or unenforceability of any such covenant or provision as written shall not invalidate or render unenforceable the remaining covenants or provisions hereof, and any such invalidity or unenforceability in any jurisdiction shall not invalidate or render unenforceable such covenant or provision in any other jurisdiction.
- 5.3 **Further Assurances**. Following the Closing, each of the Parties shall, and shall cause their respective Affiliates to, execute and deliver such additional documents, instruments, conveyances and assurances and take such further actions as may be reasonably required to carry out the provisions hereof and give effect to the transactions contemplated by this Agreement.

# 5.4 Tax Covenants.

- 5.4.1 <u>Tax Returns and Payment of Taxes</u>. Without the prior written consent of the Parent (which consent shall not be unreasonably withheld), no Seller shall, to the extent it may affect, or relate to, the Company, make, change or rescind any Tax election or amend any Tax Return or take any action or omit to take any action that would have the effect of increasing the Tax liability or reducing any Tax asset of the Company in respect of any Post-Closing Tax Period.
- (a) All transfer, documentary, sales, use, stamp, registration, value added and other such Taxes and fees (including any penalties and interest) incurred in connection with this Agreement and the other Transaction Documents (including any stamp or transfer Tax in respect of the Company Shares and any other similar Tax) shall be borne and paid by Fidelity when due. Fidelity shall, at its own expense, timely file any Tax Return or other document with respect to such Taxes or fees (and the Company shall reasonably cooperate with respect thereto as necessary).

- (b) The Company shall prepare, or cause to be prepared, all Tax Returns required to be filed by the Company after the Closing Date with respect to a Pre-Closing Tax Period. Any such Tax Return shall be prepared in a manner consistent with past practice (unless otherwise required by Law) and without a change of any election or any accounting method and shall be submitted by the Company to Fidelity (together with schedules, statements and, to the extent requested by Fidelity, supporting documentation) at least forty-five (45) days prior to the due date (including extensions) of such Tax Return. If Fidelity objects to any item on any such Tax Return, it shall, within ten days after delivery of such Tax Return, notify the Company in writing that it so objects, specifying with particularity any such item and stating the specific factual or legal basis for any such objection. If a notice of objection shall be duly delivered, the Company and Fidelity shall negotiate in good faith and use their reasonable best efforts to resolve such items. If the Company and Fidelity are unable to reach such agreement within ten (10) days after receipt by the Company of such notice, the disputed items shall be resolved by the Accounting Firm and any determination by the Accounting Firm shall be final. The Accounting Firm shall resolve any disputed items within twenty (20) days of having the item referred to it pursuant to such procedures as it may require. If the Accounting Firm is unable to resolve any disputed items before the due date for such Tax Return, the Tax Return shall be filed as prepared by the Company and Fidelity. The preparation and filing of any Tax Return of the Company that does not relate to a Pre-Closing Tax Period shall be exclusively within the control of the Company.
- 5.4.2 <u>Straddle Period</u>. In the case of Taxes that are payable with respect to a taxable period that begins before and ends after the Closing Date (each such period, a "**Straddle Period**"), the portion of any such Taxes that are treated as Pre-Closing Taxes for purposes of this Agreement shall be:
- (a) in the case of Taxes based upon, or related to, income or receipts, deemed equal to the amount which would be payable if the taxable year ended with the Closing Date; and
- (b) in the case of other Taxes, deemed to be the amount of such Taxes for the entire period multiplied by a fraction the numerator of which is the number of days in the period ending on the Closing Date and the denominator of which is the number of days in the entire period.
- 5.4.3 <u>Contests</u>. The Company agrees to give written notice to Fidelity of the receipt of any written notice by the Company, the Parent or any of the Company's Affiliates which involves the assertion of any claim, or the commencement of any audit or other proceeding in respect of Taxes of the Company, in respect of which an indemnity may be sought by any Parent Indemnified Party pursuant to this <u>Section 5.4</u> (a "**Tax Claim**"); provided, that failure to comply with this provision shall not affect any Parent Indemnified Party's right to indemnification hereunder. The Company or its Affiliates shall control the contest or resolution of any Tax Claim; provided, however, that the Company shall obtain the prior written consent of Fidelity (which

consent shall not be unreasonably withheld or delayed) before entering into any settlement of a claim or ceasing to defend such claim; Fidelity shall be entitled to participate in the defence of such claim and to employ counsel of its choice for such purpose, the fees and expenses of which separate counsel shall be borne solely by Fidelity.

5.4.4 <u>Cooperation and Exchange of Information</u>. Each Seller and the Company shall provide each other with such cooperation and information as either of them reasonably may request of the other in filing any Tax Return pursuant to this <u>Section 5.4</u> or in connection with any audit or other proceeding in respect of Taxes of the Company. Such cooperation and information shall include providing copies of relevant Tax Returns or portions thereof, together with accompanying schedules, related work papers and documents relating to rulings or other determinations by Taxing Authorities. Each Seller and the Company shall retain all Tax Returns, schedules and work papers, records and other documents in its possession relating to Tax matters of the Company for any taxable period beginning before the Closing Date until the date seven (7) years following the expiration of the statute of limitations of the taxable periods to which such Tax Returns and other documents relate, without regard to extensions except to the extent notified by the other Parties in writing of such extensions for the respective Tax periods. Prior to transferring, destroying or discarding any Tax Returns, schedules and work papers, records and other documents in its possession relating to Tax matters of the Company for any taxable period beginning before the Closing Date, each Seller or the Parent (as the case may be) shall provide the other Party with reasonable written notice and offer the Company or the Sellers' Representative, as the case may be, the opportunity to take custody of such materials.

5.4.5 Tax Indemnification. Fidelity shall indemnify the Company, and each Parent Indemnified Party and hold them harmless from and against (a) any Loss attributable to any breach of or inaccuracy in any representation or warranty made in Section 3.3.14; (b) any Loss attributable to any breach or violation of, or failure to fully perform, any covenant, agreement, undertaking or obligation in Section 5.4; (c) all Pre-Closing Taxes and all Taxes of the Company arising out of or relating to the business of the Company for all Pre-Closing Tax Periods; (d) all Taxes of any member of an affiliated, consolidated, combined or unitary group of which the Company (or any predecessor of the Company) is or was a member on or prior to the Closing Date by reason of a liability under Treasury Regulation Section 1.1502-6 or any comparable provisions of foreign, state or local Law; and (e) any and all Taxes of any person imposed on the Company arising under the principles of transferee or successor liability or by Contract, relating to an event or transaction occurring before the Closing Date. In each of the above cases, together with any out-of-pocket fees and expenses (including attorneys' and accountants' fees) incurred in connection therewith. Fidelity shall reimburse the Company for any Taxes of the Company that are the responsibility of Fidelity pursuant to this Section 5.4 within ten Business Days after payment of such Taxes by the Parent or the Company. To the extent that any obligation or responsibility pursuant to Section 5.4 may overlap with an obligation or responsibility pursuant to Article 6, the provisions of this Section 5.4 shall govern.

5.4.6 <u>Refunds</u>. Any refunds of Taxes of the Company plus any interest received with respect thereto (net of any Taxes actually imposed on Parent or its Affiliates with respect to such interest) from an applicable Taxing Authority with respect to any Pre-Closing Tax Period shall be for the account of the Sellers, and shall be paid by Parent to the Fidelity (for disbursement to the Sellers) within twenty (20) Business Days after Parent, the Surviving Corporation or any of

their Affiliates receives such refund. If any refunds or any related interest previously paid to the Sellers pursuant to this <u>Section 5.4.6</u> is required to be repaid to a Taxing Authority or is subsequently disallowed by a Taxing Authority, the Sellers shall be required to repay to Parent such previously paid amounts, together with any interest and penalties due to such Taxing Authority.

- 5.4.7 <u>Tax Treatment of Payments.</u> Any Contingent Payment actually paid pursuant to <u>Section 2.3</u> or indemnification payments pursuant to this <u>Section 5.4</u> shall be treated as an adjustment to the Merger Consideration by the parties for Tax purposes, unless otherwise required by Applicable Law.
- 5.4.8 <u>Survival</u>. Notwithstanding anything in this Agreement to the contrary, the provisions of <u>Section 3.3.14</u> and this <u>Section 5.4</u> shall survive for the full period of all applicable statutes of limitations (giving effect to any waiver, mitigation or extension thereof) plus 60 days.
- 5.5 **Public Disclosures**. No disclosure of the existence, or the terms, of this Agreement may be made by any Party, and no Party shall use the name, trademark, trade name or logo of any other Party, its Affiliates or their respective employee(s) in any publicity, promotion, press release or disclosure relating to this Agreement or its subject matter, or any Ancillary Agreement without the prior express written permission of the other Parties, except as may be required by Applicable Law. Notwithstanding the foregoing, the Parties have agreed to (a) allow disclosure of this Agreement and the Ancillary Agreements to each Party's insurers and to existing or potential equity investors and debt providers, provided that such Third Parties are bound by confidentiality restrictions at least as stringent as those contained in this Section 5.1, and (b) allow disclosure of the existence of this Agreement to its employees and vendors and for internal communications.

# 6. INDEMNIFICATION.

6.1 **Survival**. The representations and warranties of the Parties contained in this Agreement, or in any certificate or other writing delivered pursuant hereto or thereto or in connection herewith or therewith shall survive until eighteen months from the Closing Date (the "**Expiration Date**"), except that the representations and warranties in <u>Sections 3.1.1</u>, <u>3.1.2</u>, <u>3.1.6</u>, <u>3.2.1</u>, <u>3.2.2</u>, <u>3.2.3</u>, <u>3.2.7</u>, <u>3.3.1</u>, <u>3.3.2</u>, <u>3.3.3</u>, <u>3.3.3</u>, <u>3.3.1</u>, <u>3.4.1</u>, <u>3.4.2</u>, <u>3.4.3</u>, <u>3.4.8</u> and <u>3.5.4</u>, (the "**Special Representations**") shall survive until 30 days following expiration of all statutes of limitation applicable to the matters referred to therein. Notwithstanding the preceding sentence, any representation or warranty in respect of which indemnification may be sought under <u>Sections 6.2</u> or <u>6.3</u> herein shall survive the time at which it would otherwise terminate pursuant to the preceding sentence if notice of the inaccuracy or breach or potential liability thereof giving rise to such right to indemnity, with reasonable detail to allow the receiving Party to make an assessment thereof, shall have been given to the Party against whom such indemnity may be sought prior to the Expiration Date. Except for the Special Representations, no claim for indemnity for breaches of representations and warranties under this Agreement may be made after the Expiration Date. The covenants, agreements and other provisions contained in this Agreement shall survive the Closing for the full period of all applicable statutes of limitations plus 60 days. The representations and warranties and covenants and agreements contained in this Agreement (and any right to indemnification for breach thereof) shall not be affected by any investigation conducted by or on behalf of an Indemnified Party or any knowledge acquired (or capable of being acquired) by an Indemnified Party, whether before or after the Closing Date, with respect to the inaccuracy or breach of any such representation or warranty or covenant or agreement.

6.2 **Indemnification by the Parent**. Subject to the limitations set forth in Section 6.4, the Parent shall indemnify, defend and hold harmless each Seller, severally as to such Seller, their respective Affiliates, and, as applicable, their respective employees, officers, directors and agents (each, an "**Seller Indemnified Party**") from and against any and all Losses to the extent resulting from or arising out of (a) (i) any misrepresentation or breach of warranty made by Merger Sub or the Parent pursuant to the provisions of this Agreement (other than Special Representations), the Ancillary Agreements or any certificate or other writing delivered pursuant hereto or thereto and (ii) any misrepresentation or breach of any Special Representation made by Merger Sub or the Parent, or (b) any failure by Merger Sub or the Parent to fully perform, fulfill or comply with any covenant or agreement set forth herein, in the Ancillary Agreements or any certificate or other writing delivered pursuant hereto or thereto; provided that no Seller Indemnified Party shall be entitled to any duplicative recovery for the same Loss under this Section 6.2 to the extent that any Seller Indemnified Party has been actually compensated for such Loss.

# 6.3 Indemnification by the Sellers.

6.3.1 <u>Fidelity</u>. Subject to the limitations set forth in <u>Section 6.4</u>, Fidelity shall indemnify, defend and hold harmless Merger Sub (and, following the Effective Time, its successor, the Company), the Parent and their respective employees, officers, directors, agents and Affiliates (each, a "**Parent Indemnified Party**") from and against any and all Losses to the extent resulting from or arising out of (a) (i) any misrepresentation or breach of warranty made by the Company or Fidelity pursuant to the provisions of this Agreement (other than Special Representations), the Ancillary Agreements or any certificate or other writing delivered pursuant hereto or thereto and (ii) any misrepresentation or breach of any Special Representation made by the Company or Fidelity, (b) any failure by the Company or Fidelity at or prior to the Closing to fully perform, fulfill or comply with any covenant or agreement set forth herein, in the Ancillary Agreements or any certificate or other writing delivered pursuant hereto or thereto, and (c) the Company's ownership of any of the Company Assets or the operation of the business of the Company prior to the Closing; provided that no Parent Indemnified Party shall be entitled to any duplicative recovery for the same Loss under this <u>Section 6.3.1</u> to the extent that any Parent Indemnified Party has been actually compensated for such Loss.

6.3.2 <u>Brandeis</u>. Subject to the limitations set forth in <u>Section 6.4</u>, Brandeis shall indemnify and hold harmless the Parent Indemnified Parties from and against any and all Losses to the extent resulting from or arising out of (a) (i) any misrepresentation or breach of warranty made by Brandeis pursuant to the provisions of this Agreement (other than Special Representations), the Ancillary Agreements or any certificate or other writing delivered pursuant hereto or thereto and (ii) any misrepresentation or breach of any Special Representation made by Brandeis, or (b) any breach or nonperformance of any covenant or agreement of Brandeis contained herein or the Transaction Documents to which it is or will be a party; provided that no Parent Indemnified Party shall be entitled to any duplicative recovery for the same Loss under this <u>Section 6.3.2</u> to the extent that any Parent Indemnified Party has been actually compensated for such Loss.

- 6.3.3 <u>Petsko</u>. Subject to the limitations set forth in <u>Section 6.4</u>, Petsko shall indemnify and hold harmless the Parent Indemnified Parties from and against any and all Losses to the extent resulting from or arising out of (a) (i) any misrepresentation or breach of warranty made by Petsko pursuant to the provisions of this Agreement (other than Special Representations), the Ancillary Agreements or any certificate or other writing delivered pursuant hereto or thereto and (ii) any misrepresentation or breach of any Special Representation made by Petsko, or (b) any breach or nonperformance of any covenant or agreement of Petsko contained herein or the Transaction Documents to which he is or will be a party; provided that no Parent Indemnified Party shall be entitled to any duplicative recovery for the same Loss under this <u>Section 6.3.3</u> to the extent that any Parent Indemnified Party has been actually compensated for such Loss.
- 6.3.4 <u>Ringe</u>. Subject to the limitations set forth in <u>Section 6.4</u>, Ringe shall indemnify and hold harmless the Parent Indemnified Parties from and against any and all Losses to the extent resulting from or arising out of (a) (i) any misrepresentation or breach of warranty made by Ringe pursuant to the provisions of this Agreement (other than Special Representations), the Ancillary Agreements or any certificate or other writing delivered pursuant hereto or thereto and (ii) any misrepresentation or breach of any Special Representation made by Ringe, or (b) any breach or nonperformance of any covenant or agreement of Ringe contained herein or the Transaction Documents to which she is or will be a party; provided that no Parent Indemnified Party shall be entitled to any duplicative recovery for the same Loss under this <u>Section 6.3.4</u> to the extent that any Parent Indemnified Party has been actually compensated for such Loss.
- 6.3.5 For purposes of this <u>Article 6</u>, "Material Adverse Effect" qualifications and other qualifications based on the word "material" or similar phrases contained in such representations and warranties shall be disregarded for all purposes with respect to any indemnity pursuant to this <u>Section 6.3</u>, including for determining whether there is a claim and the amount of any Loss.
- 6.3.6 No Seller Indemnified Party will make any claim for indemnification against the Company, the Parent or any other Affiliate of the Company (determined after the Closing) under the certificate of incorporation or bylaws of the Company, Delaware Law, any insurance policy or otherwise by reason of the fact that such Seller Indemnified Party was a stockholder, director, manager, officer, employee or agent of the Company or is or was serving at the request of any of the Company as a partner, member, manager, trustee, director, officer, employee or agent of another entity (whether such claim is for judgments, damages, penalties, fines, costs, amounts paid in settlement, losses or expenses) with respect to any action, suit, proceeding, complaint, claim or demand brought by a Parent Indemnified Party against any Seller or the Sellers collectively (in each case, if such action, suit, proceeding, complaint, claim or demand arises under this Agreement). Each Seller Indemnified Party hereby acknowledges that it will have no claims or right to contribution or indemnity from the Company, the Parent or any other Affiliate of the Company (determined after the Closing) under the certificate of incorporation or bylaws of the Company, Delaware Law, any insurance policy or otherwise with respect to amounts payable by any Seller Indemnified Party pursuant to this Agreement (including pursuant to Sections 2.3 or the applicable provision of this Section 6.3) or any of the other Transaction Documents.

- 6.4 **Limitation of Indemnification**. The term "**Indemnified Party**" as used in this <u>Section 6.4</u> shall refer to Seller Indemnified Party or Parent Indemnified Party as applicable.
- 6.4.1 <u>Threshold Amount; Limitations</u>. No claim may be made by any Indemnified Party for indemnification pursuant to <u>Section 6.2(a)(i)</u>, <u>Section 6.3.1(a)(i)</u>, <u>Section 6.3.2(a)(i)</u>, <u>Section 6.3.3(a)(i)</u>, or <u>Section 6.3.4(a)(i)</u> herein unless and until the aggregate amount of Losses for which the Indemnified Party seeks to be indemnified exceeds ten thousand dollars (\$10,000.00), and then, only to the extent of such excess.

6.4.2 Cap.

- (a) <u>Parent</u>. The maximum liability of Parent for all claims of the Seller Indemnified Parties made pursuant to <u>Section 6.2(a)(i)</u> shall not exceed five hundred thousand dollars (\$500,000.00).
- (b) <u>Fidelity</u>. The maximum liability of Fidelity for all claims made pursuant to <u>Section 6.3.1(a)(i)</u> shall not exceed five hundred thousand dollars (\$500,000.00).
- (c) <u>Brandeis; Ringe; Petsko</u>. The maximum liability for each of Brandeis, Ringe and Petsko for any liability under this Agreement (including indemnification liability under this <u>Article 6)</u> shall not exceed the value of the portion of the Parent Shares received by such Seller (as hereinafter determined) *plus* the amount of Contingent Payments, if any, actually received by such party under <u>Section 2.3</u>, after reducing such amount by any Tax payment made by such party in connection with such Contingent Payment (including any amount withheld with respect to such Contingent Payments pursuant to <u>Section 2.5</u>).
- 6.4.3 <u>Insurance</u>. Any Losses as to which indemnification provided for in <u>Section 6.2</u> and <u>Section 6.3</u> may apply shall be determined net of any cash recovery actually received by an Indemnified Party with respect to insurance specifically with respect to the specific matter for which indemnification is sought, less any costs actually incurred in obtaining such recovery (including premium adjustments and similar charges).
- 6.4.4 Exclusive Remedy. Except for actions or claims for fraud, actions or claims brought under the provisions of Section 5.4, or actions or claims in respect of breaches of Sections 5.1, 5.2, 5.3 or 5.5 after the Closing, this Article 6 shall provide the sole and exclusive remedy for any misrepresentation or breach of any representation and warranty pursuant to the provisions of this Agreement or any certificate or other writing delivered pursuant hereto.
  - 6.4.5 Payment of Claims.
    - (a) Fidelity. Any claims made by a Parent Indemnified Party against Fidelity shall be satisfied by a cash payment from Fidelity.
- (b) <u>Brandeis</u>, <u>Petsko and Ringe</u>. Any claims made by a Parent Indemnified Party against Brandeis, Petsko or Ringe shall be satisfied first by the transfer of the Parent Shares held by Brandeis, Petsko or Ringe, respectively, back to Parent at the fair market value of the Parent Shares as of the date (the "**Return Date**") the amount of Losses in respect of which any Parent Indemnified Party is entitled to indemnification from such Seller pursuant to the

applicable subsection of <u>Section 6.3</u> applicable to such Seller has been finally determined pursuant to the provisions of <u>Section 6.5</u> or <u>Section 6.6</u>, as applicable, in accordance with the provisions set forth in the following sentence, with the balance, if any, satisfied pursuant to the setoff, recoupment or deduction of any Milestone Payment or Royalty Payment in accordance with the provisions of <u>Section 6.4.6</u> below. The fair market value of the Parent Shares as of the Return Date shall be determined as follows:

- (i) If the Return Date is within 180 days of the closing of a Qualified Financing, then the fair market value of the Parent Shares as of the Return Date shall be equal to the value of the shares offered in the Qualified Financing.
- (ii) If the Return Date is more than 180 days after the closing of a Qualified Financing, then the fair market value of the Parent Shares as of the Return Date shall be determined as follows:
- (A) If a 409A Valuation (as herein defined) is available as of the Return Date, then the fair market value of the Parent Shares as of the Return Date shall equal the value of the Parent Shares determined by an independent Third Party valuation that satisfies the safe harbor requirements under section 409A of the Code (a "409A Valuation"); or
- (B) If there is no 409A Valuation of the Parent Shares available as of the Return Date, then Brandeis, Petsko or Ringe (as applicable), on the one hand, and the Parent, on the other, shall propose in writing within thirty (30) days after the Return Date his, her or its determination of the fair market value of the Parent Shares as of the Return Date, and
- (1) If the difference between the fair market value as determined by Brandeis, Petsko or Ringe, as applicable, and the Parent is 20% or less, then the fair market value of the Parent Shares as of the Return Date shall be mid-point between the two valuations;
- (2) If the difference between the fair market value as determined by Brandeis, Petsko or Ringe, as applicable, and the Parent is more than 20%, then (i) either Party may submit the disputed fair market value of the Parent Shares as of the Return Date to the Accounting Firm for a determination pursuant to the procedures of Section 2.3.3(b) of this Agreement, the provisions of which shall apply hereto mutatis mutandis, (ii) Brandeis, Petsko or Ringe (as applicable), on the one hand, and the Parent, on the other, may agree in writing to use the mid-point between their applicable valuations, or (iii) the applicable Parties may otherwise agree in writing to a value for the Parent Shares as of the Return Date, in each case, with respect to clauses (ii) and (iii), which agreement shall be made within ten (10) Business Days after the expiration of the 30-day period pursuant to Section 6.4.5(b)(ii)(B) (or such longer period as the applicable Parties may mutually agree upon). To the extent any Party submits a matter to the Accounting Firm pursuant to clause (i) above, Brandeis and not Fidelity shall serve as Sellers' Representative with respect to such matter and Fidelity shall not have any obligation under Section 2.3.3 of this Agreement to pay any fees, costs or expenses of the Accounting Firm with respect to such matter (in which case, such obligations, if any, shall become the obligations of Brandeis, Petsko and Ringe, subject to and in accordance with the provisions of Section 2.3.3).

(c) Parent. Any claims made by a Seller Indemnified Party against Parent shall be satisfied by a cash payment from Parent.

6.4.6 Setoff Against Milestone Payment and Royalty Payments. The Parent Indemnified Parties may, at their election, setoff, recoup and deduct from all or any portion of any Milestone Payment or Royalty Payment payable to a particular Seller (directly or through the Sellers' Representative on behalf of all of the Sellers under Section 2.3 of this Agreement), the amount of Losses in respect of which any Parent Indemnified Party is entitled to indemnification from such Seller pursuant to Section 5.4 (solely with respect to Fidelity) or the applicable subsection of Section 6.3 applicable to such Seller and, in each case, as has been finally determined pursuant to the provisions of Section 6.5 or Section 6.6, as applicable, or is being contested in good faith by the Parent Indemnified Parties and such Seller (up to the entire amount of the portion of such Milestone Payment or Royalty Payment that becomes payable to such Seller, but in no event in excess of the amount of Losses in respect of which any Parent Indemnified Party is entitled to or seeking indemnification). The Parent Indemnified Parties shall exercise the foregoing rights by notifying the Sellers' Representative or the applicable Seller that it is reducing the amount of any Milestone Payment or Royalty Payment payable to the Sellers or a Seller under Section 2.3 of this Agreement and specifying in reasonable detail (i) the nature of the claim and (ii) the amount of the claimed Losses in respect of each such claim. The setoff, recoupment and deduction of any Milestone Payment or Royalty Payment payable to the Sellers under Section 2.3 of this Agreement shall not be the Parent Indemnified Parties sole method of collection or payment for any Losses in respect of which any Parent Indemnified Parties setoff, recoup, or deduct under this section and it is determined that the Parent Indemnified Parties did not have a right to setoff, recoup or deduct part or all of such funds payable to a Seller or Sellers, then, immediately upon such a determination, the Paren

6.4.7 <u>Limited Consequential Loss Exclusion</u>. (a) No Parent Indemnified Party shall be entitled to indemnification from Brandeis, Petsko or Ringe pursuant to <u>Section 6.3.2</u>, <u>Section 6.3.3</u>, or <u>Section 6.3.4</u>, respectively, and (b) neither Brandeis, Petsko or Ringe nor any of their respective Affiliates, employees, officers, directors, heirs and agents (collectively, the "**Brandeis Indemnified Parties**"), shall be entitled to indemnification from Parent pursuant to <u>Section 6.2</u>, in each case, with respect to clauses (a) and (b), for any Losses under this Agreement that constitute special, exemplary, incidental, indirect, punitive or consequential damages (including lost profits) incurred by Third Parties and for which an Indemnified Party is entitled to indemnification for a Third Party Claim under <u>Section 6.3.2 Section 6.3.3</u>, <u>Section 6.3.4</u> or <u>Section 6.2</u> of this Agreement, as applicable. For the avoidance of doubt, nothing set forth in this <u>Section 6.4.7</u> shall limit or be construed to affect the indemnification obligations of the Parent to Fidelity or any of its Affiliates, employees, officers, directors, or agents pursuant to <u>Section 6.2</u> or Fidelity pursuant to <u>Section 6.3.1</u>.

# 6.5 Third Party Claims.

6.5.1 Procedure. Promptly after the discovery by the Party seeking indemnification under Section 6.2 or Section 6.3 herein (the "Indemnified" Party") of any Loss, claim or breach, including any claim by a Third Party (a "Third Party Claim") that would reasonably be expected to give rise to a claim for indemnification hereunder, the Indemnified Party shall give written notice to the Party against whom indemnity is sought (the "Indemnifying Party"); provided that, no delay on the part of the Indemnified Party in notifying the Indemnifying Party shall relieve the Indemnifying Party of any liability or obligation hereunder, except to the extent that the Indemnifying Party has been prejudiced thereby, and then only to such extent. The Indemnifying Party shall assume the defense of the Third Party Claim and retain reputable counsel reasonably satisfactory to the Indemnified Party to represent the Indemnifying Party and the Indemnifying Party shall pay the fees and expenses of such counsel related to such proceeding. In any such proceeding, the Indemnified Party shall have the right to retain its own counsel, but the fees and expenses of such counsel shall be at the expense of the Indemnified Party unless (a) the Parties shall have mutually agreed to the retention of such counsel, (b) the named parties to any such proceeding (including any impleaded parties) include the Parties and representation of both Parties by the same counsel would be inappropriate due to actual or potential differing interests between them or (c) the Indemnified Party assumes the defense of a Third Party Claim after the Indemnifying Party has failed to diligently defend a Third Party Claim it has assumed per the Indemnified Party's request. All such fees and expenses incurred pursuant to this Section 6.5 shall be reimbursed as they are incurred. In the event that the Indemnified Party assumes the defense of any Third Party Claim, the Indemnified Party's right to indemnification for a Third Party Claim shall not be adversely affected by assuming the defense of such Third Party Claim. The Indemnifying Party shall not be liable for any settlement of any proceeding without its prior written consent (which shall not be unreasonably withheld, conditioned or delayed). The Indemnifying Party shall not, without the written consent of the Indemnified Party, effect any settlement of any Third Party Claim unless (a) such settlement includes an unconditional release of the Indemnified Party from all liability on claims to which the indemnity relates that are the subject matter of such proceeding and (b) it would not result in (i) the imposition of a consent order, injunction or decree that would restrict the future activity or conduct of the Indemnified Party or any of its Affiliates, (ii) a finding or admission of a violation of Applicable Law or violation of the rights of any Person by the Indemnified Party or any of its Affiliates or (iii) any monetary liability of the Indemnified Party arising from such Third Party Claim that shall not be promptly paid or reimbursed by the Indemnifying Party.

6.5.2 <u>Confidential Information</u>. The Indemnified Party and the Indemnifying Party shall use Commercially Reasonable Efforts to avoid production of Confidential Information (consistent with Applicable Law), and to cause all communications among employees, counsel and others representing any party to a Third Party Claim to be made so as to preserve any applicable attorney-client or work-product privileges.

6.6 **Direct Claims**. If an Indemnified Party wishes to make a claim for indemnification hereunder for a Loss that does not result from a Third Party Claim (a "**Direct Claim**"), the Indemnified Party shall notify the Indemnifying Party in writing of such Direct Claim promptly after first learning of such Direct Claim, the amount or the estimated amount of Losses sought thereunder to the extent then ascertainable (which estimate shall not be conclusive of the final

amount of such Direct Claim), any other remedy sought thereunder, any relevant time constraints relating thereto and, to the extent practicable, any other material details pertaining thereto. The Indemnifying Party shall have a period of thirty (30) business days within which to respond to such Direct Claim. If the Indemnifying Party does not respond within such thirty (30) business day period or rejects all or any part of the Direct Claim, the Indemnified Person shall be free to seek enforcement of its rights to indemnification under this Agreement with respect to such Direct Claim.

6.7 **Treatment of Indemnity Payments.** Any payment made pursuant to this <u>Article 6</u> shall be treated as an adjustment to the Merger Consideration to the extent permitted by Applicable Law.

# 7. MISCELLANEOUS.

# 7.1 Sellers' Representative.

7.1.1 The Sellers' Representative is hereby appointed and authorized to have full power and authority to represent and take actions for and on behalf of each Seller with respect to the Authorized Actions, and (x) all such actions taken by the Sellers' Representative shall be binding upon each Seller and such Seller's successors, assigns and, if applicable, heirs, as if expressly confirmed and ratified in writing by each of them and (y) no Seller shall have a right to object, dissent, protest or otherwise contest the same. Any action to be taken by any Seller or the Sellers collectively pursuant to Section 2.3 shall be authorized to be taken solely by the Sellers' Representative, except that if Fidelity shall elect in writing not to pursue a claim or objection pursuant to Section 2.3 of this Agreement that Brandeis wishes to pursue, then Brandeis shall be permitted upon written notice to Parent to assume the role of Sellers' Representative pursuant to this Section 7.1, with all of the duties, obligations, liability, rights, power and authority of the Sellers' Representative, solely to pursue and resolve such claim or objection in accordance with the terms and conditions of this Agreement. For the avoidance of doubt, to the extent Brandeis assumes the role of Sellers' Representative with respect to a claim or objection pursuant to this Section 7.1, Fidelity shall not serve as Sellers' Representative with respect to such claim or objection and Fidelity shall not have any obligation under Section 2.3.3 of this Agreement to pay any fees, costs or expenses of the Accounting Firm with respect to such claim or objection (in which case, such obligations, if any, shall become the obligations of Brandeis, Petsko and Ringe, subject to and in accordance with the provisions of Section 2.3.3).

# 7.1.2 The Sellers' Representative is hereby authorized to (the "Authorized Actions"):

- (a) receive all notices or documents given or to be given to any of the Sellers or the Sellers' Representative pursuant hereto or any other Transaction Document or in connection herewith or therewith and to receive and accept service of legal process in connection with any suit or proceeding arising under this Agreement or any other Transaction Document;
- (b) after the date of this Agreement, take such action as the Sellers' Representative may, in its sole discretion, deem appropriate in respect of: (A) receiving all documents or certificates or notices required under this Agreement or any Ancillary Agreement; and (B) all such actions as may be necessary to carry out any of the transactions contemplated by

this Agreement or any other Transaction Document, excluding any waiver of any obligation of Merger Sub or the Parent (except that the Sellers' Representative shall be authorized to waive any obligation of Parent or its Affiliates under Section 2.3 or Section 5.4, provided, however, that Seller's Representative shall not be entitled to waive the obligations of Parent or Affiliates under Section 2.3 with respect to Brandeis, Petsko or Ringe without obtaining Brandeis' prior written consent); and

- (c) engage counsel and such accountants (including the Accounting Firm) and other advisors for the purpose of carrying out the obligations of the Sellers and/or the Sellers' Representative under <u>Section 2.3</u> or <u>Section 5.4</u> and incur such expenses in connection with the foregoing.
- 7.1.3 The Sellers' Representative shall have no duties or liability to the Sellers with respect to any action taken, decision made or instruction given by the Sellers' Representative in connection with this Agreement or any instruments, documents and agreements executed and delivered in connection with this Agreement.
- 7.1.4 The Sellers, in proportion to their respective holdings of Company Shares as set forth on Schedule 2.1.5, agree to indemnify, defend and hold the Sellers' Representative and any of its Affiliates and any of their respective heirs, successors, assigns, partners, directors, officers, employees, agents, stockholders, consultants, attorneys, accountants, advisors, brokers, representatives or controlling persons, in each case relating to the Sellers' Representative's conduct as Sellers' Representative, harmless against all Losses incurred by them, other than Liabilities resulting from the Sellers' Representative's gross negligence, fraud or willful misconduct in connection with its performance under this Agreement or any instruments, documents and agreements executed and delivered in connection with this Agreement. This indemnification shall survive the termination of this Agreement. The costs of such indemnification (including the costs and expenses of enforcing this right of indemnification) shall be paid by the Sellers and no Parent Indemnified Party shall have any liability therefor. In no event shall the Sellers' Representative solely with respect to its actions or omissions in its capacity as Sellers' Representative be liable hereunder or in connection herewith for any indirect, punitive, special or consequential damages.
- 7.1.5 In the performance of its duties hereunder, the Sellers' Representative shall be entitled to (i) rely upon any document or instrument reasonably believed by its to be genuine, accurate as to content and signed by any Seller or any other Party hereunder and (ii) assume that any Person purporting to give any notice in accordance with the provisions hereof has been duly authorized to do so.
- 7.1.6 The Seller or Sellers collectively holding over a majority of the outstanding Company Shares immediately prior to the Closing shall have the right at any time following the Closing to remove the then-acting Sellers' Representative provided such Sellers appoint a successor Sellers' Representative upon the resignation or removal of the Sellers' Representative; <u>provided, however</u>, that neither the removal/resignation of the then acting Sellers' Representative nor the appointment of a successor Sellers' Representative shall be effective until the delivery to the Company of executed counterparts of a writing signed by the Sellers collectively holding over a majority of the Company Shares outstanding immediately prior to the Closing with respect to

such removal, resignation and appointment, together with an acknowledgement signed by the successor Sellers' Representative appointed in such writing that he or it accepts the responsibility of successor Sellers' Representative and agrees to perform and be bound by all of the provisions of this Agreement applicable to the Sellers' Representative. Each successor Sellers' Representative shall have all of the power, authority, rights and privileges conferred by this Agreement upon the original Sellers' Representative, and in this Agreement or any instruments, documents and agreements executed and delivered in connection with this Agreement and shall be deemed to include any interim or successor Sellers' Representative.

- 7.1.7 Subject to the right of removal under <u>Section 7.16</u>, the appointment of the Sellers' Representative hereunder is irrevocable and any action taken by the Sellers' Representative pursuant to the authority granted in this <u>Section 7.1.9</u> shall be effective and absolutely binding as the action of the Sellers' Representative under this Agreement or any instruments, documents and agreements executed and delivered in connection with this Agreement.
  - 7.2 Governing Law, Jurisdiction; Specific Performance.
- 7.2.1 <u>Governing Law</u>. The interpretation and construction of this Agreement shall be governed by the laws of the State of New York, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction.
- 7.2.2 <u>Jurisdiction</u>. With respect to any dispute, claim, controversy or proceeding arising out of or relating to this Agreement, any Ancillary Agreement or any of the transactions contemplated hereby or thereby (each, an "**Action**"), each Party irrevocably (i) agrees and consents to be subject to the jurisdiction of the United States District Court for the Southern District of New York or any New York State court sitting in New York City and (ii) waives any objection which it may have at any time to the laying of venue of any such Action brought in any such court, waives any claim that such dispute, claim, controversy or proceeding has been brought in an inconvenient forum and further waives the right to object, with respect to such Action, that such court does not have any jurisdiction over such Party.
- 7.2.3 <u>WAIVER OF JURY TRIAL</u>. THE PARTIES HERETO HEREBY IRREVOCABLY WAIVE, AND AGREE TO CAUSE THEIR RESPECTIVE SUBSIDIARIES TO WAIVE, THE RIGHT TO TRIAL BY JURY IN ANY ACTION DIRECTLY OR INDIRECTLY ARISING OUT OF, UNDER OR IN CONNECTION WITH THIS AGREEMENT, ANY ANCILLARY AGREEMENT OR ANY TRANSACTIONS CONTEMPLATED HEREBY OR THEREBY.
- 7.2.4 <u>Specific Performance</u>. Notwithstanding anything in Agreement to the contrary, the Parties agree that irreparable damage would occur and that the parties would not have any adequate remedy at law in the event that the obligations of the parties to effect, on the terms and conditions set forth herein, the covenants and agreements set forth in <u>Article V</u> of this Agreement were not performed in accordance with their specific terms or were otherwise breached. It is accordingly agreed that the Parties shall be entitled to seek an injunction or injunctions to prevent such (and only such) actual or threatened breaches of this Agreement and to enforce specifically (without proof of actual damages or harm, and not subject to any requirement

for the securing or posting of any bond in connection therewith) such terms and provisions of this Agreement in the United States District Court for the Southern District of New York or any New York State court sitting in New York County, this being in addition to any other remedy to which they are entitled at law or in equity, including money damages.

7.3 **Waiver**. A Party's failure to enforce, at any time or for any period of time, any provision of this Agreement, or to exercise any right or remedy shall not constitute a waiver of that provision, right or remedy or prevent such Party from enforcing any or all provisions of this Agreement and exercising any rights or remedies. To be effective any waiver must be in writing.

# 7.4 Notices.

7.4.1 Notice Requirements. Any notice, request, demand, waiver, consent, approval or other communication permitted or required under this Agreement shall be in writing, shall refer specifically to this Agreement and shall be deemed given only if delivered by hand or sent by facsimile transmission (with transmission confirmed) or by internationally recognized overnight delivery service that maintains records of delivery, addressed to the Parties at their respective addresses specified in Section 7.4.2 or to such other address as the Party to whom notice is to be given may have provided to the other Party in accordance with this Section 7.4.1. Such Notice shall be deemed to have been given as of the date delivered by hand or on the second Business Day (at the place of delivery) after deposit with an internationally recognized overnight delivery service.

#### 7.4.2 Address for Notice.

For Parent:

MeiraGTx Limited 450 East 29th Street, 5th Floor New York, New York 10016 Attn: Richard Giroux, Chief Operating Officer

Fax: (646) 666-7978

with a copy to:

DLA Piper LLP (US) 1251 Avenue of the Americas 27th Floor New York, New York 10020 Attn: Penny J. Minna, Esq. Fax: (410) 580-3228

and

MeiraGTx Limited 450 East 29th Street, 5th Floor New York, New York 10016

Attn: Office of the Chief Counsel

Fax: (646) 666-7978

For the Sellers' Representative:

F-Prime Inc.

(f/k/a Fidelity Biosciences Corp.)

One Main Street

Cambridge, MA 02142 Attn: Stacie Weninger Barnes Facsimile: (617) 231-2425

with a copy to:

Allan S. Galper Senior Legal Counsel FMR LLC (Fidelity Investments) 82 Devonshire St., MZ EPC 13A Boston, Massachusetts 02109

Fax: (617) 385-2001

For the Sellers:

The address of such Seller set forth on the signature pages to this Agreement.

7.5 **Entire Agreement**. This Agreement, the Schedules and the Ancillary Agreements constitute the entire agreement between the Parties with respect to the subject matter of this Agreement and the Ancillary Agreements. This Agreement and the Ancillary Agreements supersede all prior agreements, whether written or oral, with respect to the subject matter hereof and thereof (provided that, for the avoidance of doubt, the foregoing shall not affect the Confidentiality Agreements or the Parent Shareholder Agreement). All Schedules or Exhibits referred to in this Agreement are intended to be and are hereby specifically incorporated into and made a part of this Agreement. In the event of any inconsistency between any such Schedules or Exhibits and this Agreement, the terms of this Agreement shall govern.

7.6 **Amendment**. Any amendment or modification of this Agreement must be in writing and signed by authorized representatives of both Parties.

7.7 **Assignment**. No Party may assign its rights or delegate its obligations under this Agreement, in whole or in part without the prior written consent of the other Parties, except that the Parent and, following the Effective Time, the Company may make such an assignment or delegation without the consent of the Sellers or the Sellers' Representative (i) to Affiliates, provided that such assignment or delegation shall not relieve such assigning Party from its obligations hereunder, or (ii) to a successor to substantially all of the business to which this Agreement pertains, whether in a merger, sale of stock, sale of assets, spin-off or other transaction (provided that, for the avoidance of doubt, any assignment following the Effective Time of the obligations of the Company under this Agreement without a corresponding assignment of the

obligations of Parent hereunder shall not affect any of the then-remaining rights and obligations of Parent under this Agreement). Any permitted successor or assignee of rights and/or obligations hereunder shall, in writing to the other Parties, expressly assume performance of such rights and/or obligations. Any attempted assignment or delegation in violation of this <u>Section 7.7</u> shall be void.

- 7.8 **No Benefit to Others**. The provisions of this Agreement are for the sole benefit of the Parties and their successors and permitted assigns, and they shall not be construed as conferring any rights in any other Persons, except as otherwise expressly provided in this Agreement.
- 7.9 **Counterparts**. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original and all of which taken together shall be deemed to constitute one and the same instrument. An executed signature page of this Agreement delivered by facsimile or PDF transmission shall be as effective as an original executed signature page.
- 7.10 **Severability**. To the fullest extent permitted by Applicable Law, the Parties waive any provision of law that would render any provision in this Agreement invalid, illegal or unenforceable in any respect. If any provision of this Agreement is held to be invalid, illegal or unenforceable, in any respect, then such provision will be given no effect by the Parties and shall not form part of this Agreement. To the fullest extent permitted by Applicable Law and if the rights or obligations of any Party will not be materially and adversely affected, all other provisions of this Agreement shall remain in full force and effect and the Parties will use their best efforts to negotiate a provision in replacement of the provision held invalid, illegal or unenforceable that is consistent with Applicable Law and achieves, as nearly as possible, the original intention of the Parties.
- 7.11 **Expenses**. Except as otherwise provided herein, all costs and expenses incurred in connection with this Agreement shall be paid by the Party incurring such cost or expense.

# 7.12 Interpretation and Construction.

- 7.12.1 Unless otherwise provided herein, all monetary values stated herein are expressed in United States currency and all references to "dollars" or "\$" will be deemed references to the lawful money of the United States. Each accounting term set forth herein and not otherwise defined shall have the meaning accorded it under U.S. GAAP. For the avoidance of doubt, in the event of any discrepancy between U.S. GAAP and the provisions of this Agreement, the provisions of this Agreement shall control. Whenever conversion of values from any Foreign Currency for a particular date or period shall be required, such conversion shall be made using the closing exchange rate for the date that is three Business Days prior to the applicable date or dates, as the case may be, as reported by Bloomberg L.P. (the "Exchange Rate") on the close of business in New York, New York three Business Days prior to the applicable date or dates.
- 7.12.2 The parties have participated jointly in the negotiation and drafting of this Agreement. In the event an ambiguity or question of intent or interpretation arises, this Agreement shall be construed as if drafted jointly by the parties and no presumption or burden of proof shall arise favoring or disfavoring any Party by virtue of the authorship of any of the provisions of this Agreement. Any reference to any federal, state, local or foreign Law shall be deemed also to refer to all rules and regulations promulgated thereunder, unless the context requires otherwise. When a reference is made in this Agreement to a party or to a Section, Exhibit or Schedule, such reference

shall be to a Party to, a Section of, or an Exhibit or Schedule to, this Agreement, unless otherwise indicated. All terms defined in this Agreement shall have their defined meanings when used in any Exhibit or Schedule to this Agreement or any certificate or other document made or delivered pursuant hereto, unless otherwise defined therein.

- 7.12.3 Whenever the words "include", "includes", "including" or "such as" are used in this Agreement, they shall be deemed to be followed by the words "without limitation". The word "will" shall be construed to have the same meaning and effect as the word "shall". The words "hereof", "herein" and "hereunder" and words of similar import when used in this Agreement shall refer to this Agreement as a whole and not to any particular provision of this Agreement. Except where the context otherwise requires, wherever used, the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders and the word "or" is used in the inclusive sense (and/or). The word "extent" in the phrase "to the extent" means the degree to which a subject or other thing extends, and such phrase shall not mean simply "if". The words "asset" and "property" shall be construed to have the same meaning and effect.
- 7.12.4 The captions of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement.
- 7.12.5 Any agreement, instrument or statute defined or referred to herein means such agreement, instrument or statute as from time to time amended, supplemented or modified, including (a) (in the case of agreements or instruments) by waiver or consent and (in the case of statutes) by succession of comparable successor statutes and (b) all attachments thereto and instruments incorporated therein.
  - 7.12.6 References to a Person are also to its permitted successors and assigns.
- 7.13 **Opportunity to Consult Counsel.** Each Party represents that it has had the opportunity to consult with independent legal counsel or other advisors of its own choosing concerning this Agreement and the Ancillary Agreements to which it is or will be a party.

# [Signature Page Follows]

IN WITNESS WHEREOF, duly authorized representatives of the Parties have duly executed this Agreement to be effective as of the Effective Date.

# **MERGER SUB:**

# MEIRAGTx ACQUISITION CORPORATION

By /s/ Richard Giroux
Name: Richard Giroux

Title: COO

PARENT:

# MEIRAGTx LIMITED

By /s/ Zandy Forbes
Name: Zandy Forbes

Title: CEO and Director

[Signatures continued on the following page.]

# **COMPANY:**

BRI-ALZAN, INC.

By /s/ Stacie Weninger Barnes

Name: Stacie Weninger Barnes Title: President

inc. includi

# **SELLERS:**

F-PRIME INC

(f/k/a FIDELITY BIOSCIENCES CORP.)

By /s/ Mary Pendergast

Name: Mary Pendergast

Title: CFO

Address: One Main Street, 13th Floor

Cambridge, Massachusetts 02142

/s/ Gregory Petsko

Name: Gregory Petsko

Address: 308 East 72nd St., Apt 14C

New York, New York 10021

/s/ Dagmar Ringe

Name: Dagmar Ringe

Address: 983 Memorial Drive

Cambridge, Massachusetts 02138

# **BRANDEIS UNIVERSITY**

By /s/ Rebecca Menapace

Name: Rebecca Menapace

Title: Associate Provost for Innovation

Executive Director, OTL

Address: 415 South Street

Waltham, Massachusetts 02453

[Signatures continued on the following page.]

# SELLERS' REPRESENTATIVE:

F-PRIME INC (f/k/a FIDELITY BIOSCIENCES CORP.) solely in its capacity as the Sellers' Representative,

By /s/ Mary Pendergast

Name: Mary Pendergast

Title: CFO

Address: One Main Street, 13th Floor

Cambridge, Massachusetts 02142

# MEIRAGTX HOLDINGS PLC 2018 EMPLOYEE SHARE PURCHASE PLAN

# ARTICLE I PURPOSE

The purposes of this MeiraGTx Holdings plc 2018 Employee Share Purchase Plan (as it may be amended or restated from time to time, the "*Plan*") are to assist Eligible Employees of MeiraGTx Holdings plc, an exempted company limited by shares incorporated under the laws of the Cayman Islands (the "*Company*"), and its Designated Subsidiaries in acquiring a share ownership interest in the Company pursuant to a plan which is intended to qualify as an "employee stock purchase plan" within the meaning of Section 423(b) of the Code, and to help Eligible Employees provide for their future security and to encourage them to remain in the employment of the Company and its Designated Subsidiaries.

# ARTICLE II. DEFINITIONS AND CONSTRUCTION

Wherever the following terms are used in the Plan they shall have the meanings specified below, unless the context clearly indicates otherwise. The singular pronoun shall include the plural where the context so indicates. Masculine, feminine and neuter pronouns are used interchangeably and each comprehends the others.

- 2.1 "Administrator" shall mean the entity that conducts the general administration of the Plan as provided in Article XI. The term "Administrator" shall refer to the Committee unless the Board has assumed the authority for administration of the Plan as provided in Article XI.
- 2.2 "Applicable Law" shall mean the requirements relating to the administration of equity incentive plans under Cayman Islands and U.S. federal and state securities, tax and other applicable laws, rules and regulations, the applicable rules of any stock exchange or quotation system on which the Ordinary Shares are listed or quoted and the applicable laws and rules of any other country or jurisdiction where rights under this Plan are granted or governed.
  - 2.3 "*Board*" shall mean the Board of Directors of the Company.
  - 2.4 "Change in Control" shall mean and include each of the following:
- (a) A transaction or series of transactions (other than an offering of Ordinary Shares to the general public through a registration statement filed with the Securities and Exchange Commission or a transaction or series of transactions that meets the requirements of clauses (i) and (ii) of subsection (c) below) whereby any "person" or related "group" of "persons" (as such terms are used in Sections 13(d) and 14(d)(2) of the Exchange Act) (other than the Company, any of its Subsidiaries, an employee benefit plan maintained by the Company or any of its Subsidiaries or a "person" that, prior to such transaction, directly or indirectly controls, is controlled by, or is under common control with, the Company) directly or indirectly acquires beneficial ownership (within the meaning of Rule 13d-3 under the Exchange Act) of securities of the Company possessing more than 50% of the total combined voting power of the Company's securities outstanding immediately after such acquisition; or
- (b) During any period of two consecutive years, individuals who, at the beginning of such period, constitute the Board together with any new director(s) (other than a director designated by a person who shall have entered into an agreement with the Company to effect a transaction described in subsections (a) or (c)) whose election by the Board or nomination for election by the Company's

shareholders was approved by a vote of at least two-thirds of the directors then still in office who either were directors at the beginning of the two-year period or whose election or nomination for election was previously so approved, cease for any reason to constitute a majority thereof; or

- (c) The consummation by the Company (whether directly involving the Company or indirectly involving the Company through one or more intermediaries) of (x) a merger, consolidation, reorganization, or business combination or (y) a sale or other disposition of all or substantially all of the Company's assets in any single transaction or series of related transactions or (z) the acquisition of assets or stock of another entity, in each case other than a transaction:
  - (i) which results in the Company's voting securities outstanding immediately before the transaction continuing to represent (either by remaining outstanding or by being converted into voting securities of the Company or the person that, as a result of the transaction, controls, directly or indirectly, the Company or owns, directly or indirectly, all or substantially all of the Company's assets or otherwise succeeds to the business of the Company (the Company or such person, the "Successor Entity")) directly or indirectly, at least a majority of the combined voting power of the Successor Entity's outstanding voting securities immediately after the transaction, and
  - (ii) after which no person or group beneficially owns voting securities representing 50% or more of the combined voting power of the Successor Entity; <u>provided</u>, <u>however</u>, that no person or group shall be treated for purposes of this clause (ii) as beneficially owning 50% or more of the combined voting power of the Successor Entity solely as a result of the voting power held in the Company prior to the consummation of the transaction.

The Administrator shall have full and final authority, which shall be exercised in its discretion, to determine conclusively whether a Change in Control has occurred pursuant to the above definition, the date of the occurrence of such Change in Control and any incidental matters relating thereto.

- 2.5 "Code" shall mean the Internal Revenue Code of 1986, as amended, and the regulations issued thereunder.
- 2.6 "Company" shall mean MeiraGTx Holdings plc, an exempted company limited by shares incorporated under the laws of the Cayman Islands, or any successor.
- 2.7 "*Compensation*" of an Eligible Employee shall mean the gross base compensation received by such Eligible Employee as compensation for services to the Company or any Designated Subsidiary, including overtime payments and excluding sales commissions, incentive compensation, bonuses, expense reimbursements, fringe benefits and other special payments.
  - 2.8 "Designated Subsidiary" shall mean any Subsidiary designated by the Administrator in accordance with Section 11.3(b).
  - 2.9 "Effective Date" shall mean the day prior to the Public Trading Date.
- 2.10 "*Eligible Employee*" shall mean an Employee: (a) who does not, immediately after any rights under this Plan are granted, own (directly or through attribution) shares possessing 5% or more of the total combined voting power or value of all classes of Ordinary Shares and other shares of the Company, a Parent or a Subsidiary (as determined under Section 423(b)(3) of the Code); (b) whose customary employment is for more than twenty hours per week; and (c) whose customary employment is for more than five months in any calendar year. For purposes of the foregoing, the rules of Section 424(d)

of the Code with regard to the attribution of share ownership shall apply in determining the share ownership of an individual, and shares that an Employee may purchase under outstanding options shall be treated as shares owned by the Employee; <u>provided</u>, <u>however</u>, that the Administrator may provide in an Offering Document that an Employee shall not be eligible to participate in an Offering Period if: (i) such Employee is a highly compensated employee within the meaning of Section 423(b)(4)(D) of the Code; and/or (ii) such Employee has not met a service requirement designated by the Administrator pursuant to Section 423(b)(4)(A) of the Code (which service requirement may not exceed two years), and/or (iii) such Employee is a citizen or resident of a foreign jurisdiction and the grant of a right to purchase Ordinary Shares under the Plan to such Employee would be prohibited under the laws of such foreign jurisdiction or the grant of a right to purchase Ordinary Shares under the Plan to such Employee in compliance with the laws of such foreign jurisdiction would cause the Plan to violate the requirements of Section 423 of the Code, as determined by the Administrator in its sole discretion; <u>provided</u>, <u>further</u>, that any exclusion in clauses (i), (ii) or (iii) shall be applied in an identical manner under each Offering Period to all Employees, in accordance with Treasury Regulation Section 1.423-2(e).

- 2.11 "*Employee*" shall mean any officer or other employee (as defined in accordance with Section 3401(c) of the Code) of the Company or any Designated Subsidiary. "Employee" shall not include any director of the Company or a Designated Subsidiary who does not render services to the Company or a Designated Subsidiary as an employee within the meaning of Section 3401(c) of the Code. For purposes of the Plan, the employment relationship shall be treated as continuing intact while the individual is on sick leave or other leave of absence approved by the Company or Designated Subsidiary and meeting the requirements of Treasury Regulation Section 1.421-1(h)(2). Where the period of leave exceeds three (3) months and the individual's right to reemployment is not guaranteed either by statute or by contract, the employment relationship shall be deemed to have terminated on the first day immediately following such three (3)-month period.
  - 2.12 "Enrollment Date" shall mean the first Trading Day of each Offering Period.
  - 2.13 "Exchange Act" shall mean the Securities Exchange Act of 1934, as amended.
- 2.14 "Fair Market Value" means, as of any date, the value of Ordinary Shares determined as follows: (i) if the Ordinary Shares are listed on any established stock exchange, its Fair Market Value will be the closing sales price for such Ordinary Shares as quoted on such exchange for such date, or if no sale occurred on such date, the last day preceding such date during which a sale occurred, as reported in The Wall Street Journal or another source the Administrator deems reliable; (ii) if the Ordinary Shares are not traded on a stock exchange but is quoted on a national market or other quotation system, the closing sales price on such date, or if no sales occurred on such date, then on the last date preceding such date during which a sale occurred, as reported in The Wall Street Journal or another source the Administrator deems reliable; or (iii) without an established market for the Ordinary Shares, the Administrator will determine the Fair Market Value in its discretion.
  - 2.15 "Offering Document" shall have the meaning given to such term in Section 4.1.
  - 2.16 "Offering Period" shall have the meaning given to such term in Section 4.1.
  - 2.17 "Ordinary Shares" means the ordinary shares of the Company.
- 2.18 "*Parent*" shall mean any corporation, other than the Company, in an unbroken chain of corporations ending with the Company if, at the time of the determination, each of the corporations other than the Company owns shares possessing 50% or more of the total combined voting power of all classes of shares in one of the other corporations in such chain.

- 2.19 "*Participant*" shall mean any Eligible Employee who has executed a subscription agreement and been granted rights to purchase Ordinary Shares pursuant to the Plan.
  - 2.20 "Plan" shall mean this 2018 Employee Share Purchase Plan.
- 2.21 "**Public Trading Date**" shall mean the first date upon which the Ordinary Shares are listed (or approved for listing) upon notice of issuance on any securities exchange or designated (or approved for designation) upon notice of issuance as a national market security on an interdealer quotation system, or, if earlier, the date on which the Company becomes a "publicly held corporation" for purposes of Treasury Regulation Section 1.162-27(c)(1).
  - 2.22 "Purchase Date" shall mean the last Trading Day of each Offering Period.
- 2.23 "*Purchase Price*" shall mean the purchase price designated by the Administrator in the applicable Offering Document (which purchase price shall not be less than 85% of the Fair Market Value of a Share on the Enrollment Date or on the Purchase Date, whichever is lower); <u>provided</u>, <u>however</u>, that, in the event no purchase price is designated by the Administrator in the applicable Offering Document, the purchase price for the Offering Periods covered by such Offering Document shall be 85% of the Fair Market Value of a Share on the Enrollment Date or on the Purchase Date, whichever is lower; <u>provided</u>, <u>further</u>, that the Purchase Price may be adjusted by the Administrator pursuant to Article VIII and shall not be less than the par value of a Share.
  - 2.24 "Securities Act" shall mean the Securities Act of 1933, as amended.
  - 2.25 "Share" or "Shares" means an Ordinary Share or Ordinary Shares.
- 2.26 "*Subsidiary*" shall mean any corporation, other than the Company, in an unbroken chain of corporations beginning with the Company if, at the time of the determination, each of the corporations other than the last corporation in an unbroken chain owns shares possessing 50% or more of the total combined voting power of all classes of shares in one of the other corporations in such chain; <u>provided</u>, however, that a limited liability company or partnership may be treated as a Subsidiary to the extent either (a) such entity is treated as a disregarded entity under Treasury Regulation Section 301.7701-3(a) by reason of the Company or any other Subsidiary that is a corporation being the sole owner of such entity, or (b) such entity elects to be classified as a corporation under Treasury Regulation Section 301.7701-3(a) and such entity would otherwise qualify as a Subsidiary.
  - 2.27 "Trading Day" shall mean a day on which national stock exchanges in the United States are open for trading.

# ARTICLE III. SHARES SUBJECT TO THE PLAN

3.1 Number of Shares. Subject to Article VIII, the aggregate number of Shares that may be issued pursuant to rights granted under the Plan shall be 509,166 Shares. In addition to the foregoing, subject to Article VIII, on the first day of each calendar year beginning on January 1, 2019 and ending on and including January 1, 2028, the number of Shares available for issuance under the Plan shall be increased by that number of Shares equal to the lesser of (a) 1% of the Shares outstanding on the final day of the immediately preceding calendar year and (b) such smaller number of Shares as determined by the Board. If any right granted under the Plan shall for any reason terminate without having been exercised, the Ordinary Shares not purchased under such right shall again become available for issuance under the Plan. Notwithstanding anything in this Section 3.1 to the contrary, the number of Shares that may be issued or transferred pursuant to the rights granted under the Plan shall not exceed an aggregate of 3,818,745 Shares, subject to Article VIII.

3.2 <u>Shares Distributed</u>. Any Ordinary Shares distributed pursuant to the Plan may consist, in whole or in part, of authorized and unissued Ordinary Shares, treasury shares or Ordinary Shares purchased on the open market.

# ARTICLE IV. OFFERING PERIODS: OFFERING DOCUMENTS: PURCHASE DATES

- 4.1 <u>Offering Periods</u>. The Administrator may from time to time grant or provide for the grant of rights to purchase Ordinary Shares under the Plan to Eligible Employees during one or more periods (each, an "*Offering Period*") selected by the Administrator. The terms and conditions applicable to each Offering Period shall be set forth in an "*Offering Document*" adopted by the Administrator, which Offering Document shall be in such form and shall contain such terms and conditions as the Administrator shall deem appropriate and shall be incorporated by reference into and made part of the Plan and shall be attached hereto as part of the Plan. The provisions of separate Offering Periods under the Plan need not be identical.
- 4.2 Offering Documents . Each Offering Document with respect to an Offering Period shall specify (through incorporation of the provisions of this Plan by reference or otherwise):
  - (a) the length of the Offering Period, which period shall not exceed twenty-seven months;
- (b) the maximum number of Shares that may be purchased by any Eligible Employee during such Offering Period, which, in the absence of a contrary designation by the Administrator, shall be 25,000 Shares; and
  - (c) such other provisions as the Administrator determines are appropriate, subject to the Plan.

#### ARTICLE V. ELIGIBILITY AND PARTICIPATION

5.1 <u>Eligibility</u>. Any Eligible Employee who shall be employed by the Company or a Designated Subsidiary on a given Enrollment Date for an Offering Period shall be eligible to participate in the Plan during such Offering Period, subject to the requirements of this Article V and the limitations imposed by Section 423(b) of the Code.

### 5.2 Enrollment in Plan

- (a) Except as otherwise set forth in an Offering Document or determined by the Administrator, an Eligible Employee may become a Participant in the Plan for an Offering Period by delivering a subscription agreement to the Company by such time prior to the Enrollment Date for such Offering Period (or such other date specified in the Offering Document) designated by the Administrator and in such form as the Company provides.
- (b) Each subscription agreement shall designate a whole percentage of such Eligible Employee's Compensation to be withheld by the Company or the Designated Subsidiary employing such Eligible Employee on each payday during the Offering Period as payroll deductions under the Plan. The

percentage of Compensation designated by an Eligible Employee may not be less than 1% and may not be more than the maximum percentage specified by the Administrator in the applicable Offering Document (which percentage shall be 25% in the absence of any such designation) as payroll deductions. The payroll deductions made for each Participant shall be credited to an account for such Participant under the Plan and shall be deposited with the general funds of the Company.

- (c) A Participant may increase or decrease the percentage of Compensation designated in his or her subscription agreement, subject to the limits of this Section 5.2, or may suspend his or her payroll deductions, at any time during an Offering Period; provided, however, that the Administrator may limit the number of changes a Participant may make to his or her payroll deduction elections during each Offering Period in the applicable Offering Document (and in the absence of any specific designation by the Administrator, a Participant shall be allowed one change to his or her payroll deduction elections during each Offering Period). Any such change or suspension of payroll deductions shall be effective with the first full payroll period following five business days after the Company's receipt of the new subscription agreement (or such shorter or longer period as may be specified by the Administrator in the applicable Offering Document). In the event a Participant suspends his or her payroll deductions, such Participant's cumulative payroll deductions prior to the suspension shall remain in his or her account and shall be applied to the purchase of Shares on the next occurring Purchase Date and shall not be paid to such Participant unless he or she withdraws from participation in the Plan pursuant to Article VII.
- (d) Except as otherwise set forth in an Offering Document or determined by the Administrator, a Participant may participate in the Plan only by means of payroll deduction and may not make contributions by lump sum payment for any Offering Period.
- 5.3 <u>Payroll Deductions</u>. Except as otherwise provided in the applicable Offering Document, payroll deductions for a Participant shall commence on the first payroll following the Enrollment Date and shall end on the last payroll in the Offering Period to which the Participant's authorization is applicable, unless sooner terminated by the Participant as provided in Article VII or suspended by the Participant or the Administrator as provided in Section 5.2 and Section 5.6, respectively.
- 5.4 <u>Effect of Enrollment</u>. A Participant's completion of a subscription agreement will enroll such Participant in the Plan for each subsequent Offering Period on the terms contained therein until the Participant either submits a new subscription agreement, withdraws from participation under the Plan as provided in Article VII or otherwise becomes ineligible to participate in the Plan.
- 5.5 <u>Limitation on Purchase of Ordinary Shares</u>. An Eligible Employee may be granted rights under the Plan only if such rights, together with any other rights granted to such Eligible Employee under "employee stock purchase plans" of the Company, any Parent or any Subsidiary, as specified by Section 423(b)(8) of the Code, do not permit such employee's rights to purchase shares of the Company or any Parent or Subsidiary to accrue at a rate that exceeds \$25,000 of the fair market value of such shares (determined as of the first day of the Offering Period during which such rights are granted) for each calendar year in which such rights are outstanding at any time. This limitation shall be applied in accordance with Section 423(b)(8) of the Code.
- 5.6 <u>Decrease or Suspension of Payroll Deductions</u>. Notwithstanding the foregoing, to the extent necessary to comply with Section 423(b)(8) of the Code and Section 5.5 or the other limitations set forth in this Plan, a Participant's payroll deductions may be suspended by the Administrator at any time during an Offering Period. The balance of the amount credited to the account of each Participant that has not been applied to the purchase of Shares by reason of Section 423(b)(8) of the Code, Section 5.5 or the other limitations set forth in this Plan shall be paid to such Participant in one lump sum in cash as soon as reasonably practicable after the Purchase Date.

- 5.7 <u>Foreign Employees</u>. In order to facilitate participation in the Plan, the Administrator may provide for such special terms applicable to Participants who are citizens or residents of a non-US jurisdiction, or who are employed by a Designated Subsidiary outside of the United States, as the Administrator may consider necessary or appropriate to accommodate differences in local law, tax policy or custom. Such special terms may not be more favorable than the terms of rights granted under the Plan to Eligible Employees who are residents of the United States. Moreover, the Administrator may approve such supplements to, or amendments, restatements or alternative versions of, this Plan as it may consider necessary or appropriate for such purposes without thereby affecting the terms of this Plan as in effect for any other purpose. No such special terms, supplements, amendments or restatements shall include any provisions that are inconsistent with the terms of this Plan as then in effect unless this Plan could have been amended to eliminate such inconsistency without further approval by the shareholders of the Company.
- 5.8 <u>Leave of Absence</u>. During leaves of absence approved by the Company meeting the requirements of Treasury Regulation Section 1.421-1(h)(2) under the Code, a Participant may continue participation in the Plan by making cash payments to the Company on his or her normal payday equal to his or her authorized payroll deduction.

# ARTICLE VI. GRANT AND EXERCISE OF RIGHTS

- 6.1 <u>Grant of Rights</u>. On the Enrollment Date of each Offering Period, each Eligible Employee participating in such Offering Period shall be granted a right to purchase the maximum number of Shares specified under Section 4.2, subject to the limits in Section 5.5, and shall have the right to buy, on each Purchase Date during such Offering Period (at the applicable Purchase Price), such number of whole Shares as is determined by dividing (a) such Participant's payroll deductions accumulated prior to such Purchase Date and retained in the Participant's account as of the Purchase Date, by (b) the applicable Purchase Price (rounded down to the nearest Share). The right shall expire on the last day of the Offering Period.
- 6.2 Exercise of Rights. On each Purchase Date, each Participant's accumulated payroll deductions and any other additional payments specifically provided for in the applicable Offering Document will be applied to the purchase of whole Shares, up to the maximum number of Shares permitted pursuant to the terms of the Plan and the applicable Offering Document, at the Purchase Price. No fractional Shares shall be issued upon the exercise of rights granted under the Plan, unless the Offering Document specifically provides otherwise. Any cash in lieu of fractional Shares remaining after the purchase of whole Shares upon exercise of a purchase right will be credited to a Participant's account and carried forward and applied toward the purchase of whole Shares for the next following Offering Period. Shares issued pursuant to the Plan may be evidenced in such manner as the Administrator may determine and may be issued in certificated form or issued pursuant to book-entry procedures.
- 6.3 <u>Pro Rata Allocation of Shares</u>. If the Administrator determines that, on a given Purchase Date, the number of Shares with respect to which rights are to be exercised may exceed (a) the number of Shares that were available for issuance under the Plan on the Enrollment Date of the applicable Offering Period, or (b) the number of Shares available for issuance under the Plan on such Purchase Date, the Administrator may in its sole discretion provide that the Company shall make a pro rata allocation of the Shares available for purchase on such Enrollment Date or Purchase Date, as applicable, in as uniform a manner as shall be practicable and as it shall determine in its sole discretion to be equitable among all

Participants for whom rights to purchase Ordinary Shares are to be exercised pursuant to this Article VI on such Purchase Date, and shall either (i) continue all Offering Periods then in effect, or (ii) terminate any or all Offering Periods then in effect pursuant to Article IX. The Company may make pro rata allocation of the Shares available on the Enrollment Date of any applicable Offering Period pursuant to the preceding sentence, notwithstanding any authorization of additional Shares for issuance under the Plan by the Company's shareholders subsequent to such Enrollment Date. The balance of the amount credited to the account of each Participant that has not been applied to the purchase of Shares shall be paid to such Participant in one lump sum in cash as soon as reasonably practicable after the Purchase Date.

- 6.4 <u>Withholding</u>. At the time a Participant's rights under the Plan are exercised, in whole or in part, or at the time some or all of the Ordinary Shares issued under the Plan is disposed of, the Participant must make adequate provision for the Company's federal, state, or other tax withholding obligations, if any, that arise upon the exercise of the right or the disposition of the Ordinary Shares. At any time, the Company may, but shall not be obligated to, withhold from the Participant's compensation the amount necessary for the Company to meet applicable withholding obligations, including any withholding required to make available to the Company any tax deductions or benefits attributable to sale or early disposition of Ordinary Shares by the Participant.
- 6.5 <u>Conditions to Issuance of Ordinary Shares</u>. The Company shall not be required to issue or deliver any certificate or certificates for, or make any book entries evidencing, Shares purchased upon the exercise of rights under the Plan prior to fulfillment of all of the following conditions:
  - (a) The admission of such Shares to listing on all stock exchanges, if any, on which the Ordinary Shares are then listed;
- (b) The completion of any registration or other qualification of such Shares under any state or federal law or under the rulings or regulations of the Securities and Exchange Commission or any other governmental regulatory body, that the Administrator shall, in its absolute discretion, deem necessary or advisable:
- (c) The obtaining of any approval or other clearance from any state or federal governmental agency that the Administrator shall, in its absolute discretion, determine to be necessary or advisable;
- (d) The payment to the Company of all amounts that it is required to withhold under federal, state or local law upon exercise of the rights, if any; and
- (e) The lapse of such reasonable period of time following the exercise of the rights as the Administrator may from time to time establish for reasons of administrative convenience.

### ARTICLE VII. WITHDRAWAL; CESSATION OF ELIGIBILITY

7.1 Withdrawal. A Participant may withdraw all but not less than all of the payroll deductions credited to his or her account and not yet used to exercise his or her rights under the Plan at any time by giving written notice to the Company in a form acceptable to the Company no later than one week prior to the end of the Offering Period. All of the Participant's payroll deductions credited to his or her account during an Offering Period shall be paid to such Participant as soon as reasonably practicable after receipt of notice of withdrawal and such Participant's rights for the Offering Period shall be automatically terminated, and no further payroll deductions for the purchase of Shares shall be made for such Offering Period. If a Participant withdraws from an Offering Period, payroll deductions shall not resume at the beginning of the next Offering Period unless the Participant timely delivers to the Company a new subscription agreement.

- 7.2 <u>Future Participation</u>. A Participant's withdrawal from an Offering Period shall not have any effect upon his or her eligibility to participate in any similar plan that may hereafter be adopted by the Company or a Designated Subsidiary or in subsequent Offering Periods that commence after the termination of the Offering Period from which the Participant withdraws.
- 7.3 <u>Cessation of Eligibility</u>. Upon a Participant's ceasing to be an Eligible Employee for any reason, he or she shall be deemed to have elected to withdraw from the Plan pursuant to this Article VII and the payroll deductions credited to such Participant's account during the Offering Period shall be paid to such Participant or, in the case of his or her death, to the person or persons entitled thereto under Section 12.4, as soon as reasonably practicable, and such Participant's rights for the Offering Period shall be automatically terminated.

# ARTICLE VIII. ADJUSTMENTS UPON CHANGES IN SHARES

- 8.1 <u>Changes in Capitalization</u>. Subject to Section 8.3, in the event that the Administrator determines that any dividend or other distribution (whether in the form of cash, Ordinary Shares, other securities, or other property), Change in Control, reorganization, merger, amalgamation, consolidation, combination, repurchase, recapitalization, liquidation, dissolution, or sale, transfer, exchange or other disposition of all or substantially all of the assets of the Company, or sale or exchange of Ordinary Shares or other securities of the Company, issuance of warrants or other rights to purchase Ordinary Shares or other securities of the Company, or other similar corporate transaction or event, as determined by the Administrator, affects the Ordinary Shares such that an adjustment is determined by the Administrator to be appropriate in order to prevent dilution or enlargement of the benefits or potential benefits intended by the Company to be made available under the Plan or with respect to any outstanding purchase rights under the Plan, the Administrator shall make equitable adjustments, if any, to reflect such change with respect to (a) the aggregate number and type of Shares (or other securities or property) that may be issued under the Plan (including, but not limited to, adjustments of the limitations in Section 3.1 and the limitations established in each Offering Document pursuant to Section 4.2 on the maximum number of Shares that may be purchased); (b) the class(es) and number of Shares and price per Share subject to outstanding rights; and (c) the Purchase Price with respect to any outstanding rights.
- 8.2 Other Adjustments. Subject to Section 8.3, in the event of any transaction or event described in Section 8.1 or any unusual or nonrecurring transactions or events affecting the Company, any affiliate of the Company, or the financial statements of the Company or any affiliate (including without limitation any Change in Control), or of changes in Applicable Law or accounting principles, the Administrator, in its discretion, and on such terms and conditions as it deems appropriate, is hereby authorized to take any one or more of the following actions whenever the Administrator determines that such action is appropriate in order to prevent the dilution or enlargement of the benefits or potential benefits intended to be made available under the Plan or with respect to any right under the Plan, to facilitate such transactions or events or to give effect to such changes in laws, regulations or principles:
- (a) To provide for either (i) termination of any outstanding right in exchange for an amount of cash, if any, equal to the amount that would have been obtained upon the exercise of such right had such right been currently exercisable or (ii) the replacement of such outstanding right with other rights or property selected by the Administrator in its sole discretion;

- (b) To provide that the outstanding rights under the Plan shall be assumed by the successor or survivor corporation, or a parent or subsidiary thereof, or shall be substituted for by similar rights covering the stock of the successor or survivor corporation, or a parent or subsidiary thereof, with appropriate adjustments as to the number and kind of shares and prices;
- (c) To make adjustments in the number and type of Shares (or other securities or property) subject to outstanding rights under the Plan and/or in the terms and conditions of outstanding rights and rights that may be granted in the future;
- (d) To provide that Participants' accumulated payroll deductions may be used to purchase Ordinary Shares prior to the next occurring Purchase Date on such date as the Administrator determines in its sole discretion and the Participants' rights under the ongoing Offering Period(s) shall be terminated; and
  - (e) To provide that all outstanding rights shall terminate without being exercised.
- 8.3 No Adjustment Under Certain Circumstances. No adjustment or action described in this Article VIII or in any other provision of the Plan shall be authorized to the extent that such adjustment or action would cause the Plan to fail to satisfy the requirements of Section 423 of the Code.
- 8.4 No Other Rights. Except as expressly provided in the Plan, no Participant shall have any rights by reason of any subdivision or consolidation of shares of any class, the payment of any dividend, any increase or decrease in the number of shares of any class or any dissolution, liquidation, merger, or consolidation of the Company or any other corporation. Except as expressly provided in the Plan or pursuant to action of the Administrator under the Plan, no issuance by the Company of shares of any class, or securities convertible into shares of any class, shall affect, and no adjustment by reason thereof shall be made with respect to, the number of Shares subject to outstanding rights under the Plan or the Purchase Price with respect to any outstanding rights.

# ARTICLE IX. AMENDMENT, MODIFICATION AND TERMINATION

- 9.1 <u>Amendment, Modification and Termination</u>. The Administrator may amend, suspend or terminate the Plan at any time and from time to time; <u>provided</u>, <u>however</u>, that approval of the Company's shareholders shall be required to amend the Plan to: (a) increase the aggregate number, or change the type, of shares that may be sold pursuant to rights under the Plan under Section 3.1 (other than an adjustment as provided by Article VIII); (b) change the corporations or classes of corporations whose employees may be granted rights under the Plan; or (c) change the Plan in any manner that would cause the Plan to no longer be an "employee stock purchase plan" within the meaning of Section 423(b) of the Code.
- 9.2 <u>Certain Changes to Plan</u>. Without shareholder consent and without regard to whether any Participant rights may be considered to have been adversely affected, to the extent permitted by Section 423 of the Code, the Administrator shall be entitled to change the Offering Periods, limit the frequency and/or number of changes in the amount withheld from Compensation during an Offering Period, establish the exchange ratio applicable to amounts withheld in a currency other than U.S. dollars, permit payroll withholding in excess of the amount designated by a Participant in order to adjust for delays or mistakes in the Company's processing of withholding elections, establish reasonable waiting and adjustment periods and/or accounting and crediting procedures to ensure that amounts applied toward the purchase of Ordinary Shares for each Participant properly correspond with amounts withheld from the Participant's Compensation, and establish such other limitations or procedures as the Administrator determines in its sole discretion to be advisable that are consistent with the Plan.

- 9.3 <u>Actions In the Event of Unfavorable Financial Accounting Consequences</u>. In the event the Administrator determines that the ongoing operation of the Plan may result in unfavorable financial accounting consequences, the Administrator may, in its discretion and, to the extent necessary or desirable, modify or amend the Plan to reduce or eliminate such accounting consequence including, but not limited to:
  - (a) altering the Purchase Price for any Offering Period including an Offering Period underway at the time of the change in Purchase Price;
- (b) shortening any Offering Period so that the Offering Period ends on a new Purchase Date, including an Offering Period underway at the time of the Administrator action; and
  - (c) allocating Shares.

Such modifications or amendments shall not require shareholder approval or the consent of any Participant.

9.4 <u>Payments Upon Termination of Plan</u>. Upon termination of the Plan, the balance in each Participant's Plan account shall be refunded as soon as practicable after such termination, without any interest thereon.

#### ARTICLE X. TERM OF PLAN

The Plan shall be effective on the Effective Date. The effectiveness of the Plan shall be subject to approval of the Plan by the shareholders of the Company within twelve months following the date the Plan is first approved by the Board. No right may be granted under the Plan prior to such shareholder approval. No rights may be granted under the Plan during any period of suspension of the Plan or after termination of the Plan.

# ARTICLE XI. ADMINISTRATION

- 11.1 <u>Administrator</u>. Unless otherwise determined by the Board, the Administrator of the Plan shall be the Compensation Committee of the Board (or another committee or a subcommittee of the Board to which the Board delegates administration of the Plan) (such committee, the "*Committee*"). The Board may at any time vest in the Board any authority or duties for administration of the Plan.
- 11.2 Action by the Administrator. Unless otherwise established by the Board or in any charter of the Administrator, a majority of the Administrator shall constitute a quorum. The acts of a majority of the members present at any meeting at which a quorum is present and, subject to Applicable Law and the memorandum and articles of association of the Company, acts approved in writing by a majority of the Administrator in lieu of a meeting, shall be deemed the acts of the Administrator. Each member of the Administrator is entitled to, in good faith, rely or act upon any report or other information furnished to that member by any officer or other employee of the Company or any Designated Subsidiary, the Company's independent certified public accountants, or any executive compensation consultant or other professional retained by the Company to assist in the administration of the Plan.

- 11.3 Authority of Administrator. The Administrator shall have the power, subject to, and within the limitations of, the express provisions of the Plan:
- (a) To determine when and how rights to purchase Ordinary Shares shall be granted and the provisions of each offering of such rights (which need not be identical).
- (b) To designate from time to time which Subsidiaries of the Company shall be Designated Subsidiaries, which designation may be made without the approval of the shareholders of the Company.
- (c) To construe and interpret the Plan and rights granted under it, and to establish, amend and revoke rules and regulations for its administration. The Administrator, in the exercise of this power, may correct any defect, omission or inconsistency in the Plan, in a manner and to the extent it shall deem necessary or expedient to make the Plan fully effective.
  - (d) To amend, suspend or terminate the Plan as provided in Article IX.
- (e) Generally, to exercise such powers and to perform such acts as the Administrator deems necessary or expedient to promote the best interests of the Company and its Subsidiaries and to carry out the intent that the Plan be treated as an "employee stock purchase plan" within the meaning of Section 423 of the Code.
- 11.4 <u>Decisions Binding</u>. The Administrator's interpretation of the Plan, any rights granted pursuant to the Plan, any subscription agreement and all decisions and determinations by the Administrator with respect to the Plan are final, binding, and conclusive on all parties.

# ARTICLE XII. MISCELLANEOUS

- 12.1 <u>Restriction upon Assignment</u>. A right granted under the Plan shall not be transferable other than by will or the applicable laws of descent and distribution, and is exercisable during the Participant's lifetime only by the Participant. Except as provided in Section 12.4 hereof, a right under the Plan may not be exercised to any extent except by the Participant. The Company shall not recognize and shall be under no duty to recognize any assignment or alienation of the Participant's interest in the Plan, the Participant's rights under the Plan or any rights thereunder.
- 12.2 <u>Rights as a Shareholder</u>. With respect to Shares subject to a right granted under the Plan, a Participant shall not be deemed to be a shareholder of the Company, and the Participant shall not have any of the rights or privileges of a shareholder, until such Shares have been issued to the Participant or his or her nominee following exercise of the Participant's rights under the Plan. No adjustments shall be made for dividends (ordinary or extraordinary, whether in cash securities, or other property) or distribution or other rights for which the record date occurs prior to the date of such issuance, except as otherwise expressly provided herein or as determined by the Administrator.
  - 12.3 Interest. No interest shall accrue on the payroll deductions or contributions of a Participant under the Plan.
  - 12.4 Designation of Beneficiary.
- (a) A Participant may, in the manner determined by the Administrator, file a written designation of a beneficiary who is to receive any Shares and/or cash, if any, from the Participant's

account under the Plan in the event of such Participant's death subsequent to a Purchase Date on which the Participant's rights are exercised but prior to delivery to such Participant of such Shares and cash. In addition, a Participant may file a written designation of a beneficiary who is to receive any cash from the Participant's account under the Plan in the event of such Participant's death prior to exercise of the Participant's rights under the Plan. If the Participant is married and resides in a community property state, a designation of a person other than the Participant's spouse as his or her beneficiary shall not be effective without the prior written consent of the Participant's spouse.

- (b) Such designation of beneficiary may be changed by the Participant at any time by written notice to the Company. In the event of the death of a Participant and in the absence of a beneficiary validly designated under the Plan who is living at the time of such Participant's death, the Company shall deliver such Shares and/or cash to the executor or administrator of the estate of the Participant, or if no such executor or administrator has been appointed (to the knowledge of the Company), the Company, in its discretion, may deliver such Shares and/or cash to the spouse or to any one or more dependents or relatives of the Participant, or if no spouse, dependent or relative is known to the Company, then to such other person as the Company may designate.
- 12.5 <u>Notices</u>. All notices or other communications by a Participant to the Company under or in connection with the Plan shall be deemed to have been duly given when received in the form specified by the Company at the location, or by the person, designated by the Company for the receipt thereof.
- 12.6 Equal Rights and Privileges. Subject to Section 5.7, all Eligible Employees will have equal rights and privileges under this Plan so that this Plan qualifies as an "employee stock purchase plan" within the meaning of Section 423 of the Code. Subject to Section 5.7, any provision of this Plan that is inconsistent with Section 423 of the Code will, without further act or amendment by the Company, the Board or the Administrator, be reformed to comply with the equal rights and privileges requirement of Section 423 of the Code.
- 12.7 <u>Use of Funds</u>. All payroll deductions received or held by the Company under the Plan may be used by the Company for any corporate purpose, and the Company shall not be obligated to segregate such payroll deductions.
- 12.8 <u>Reports</u>. Statements of account shall be given to Participants at least annually, which statements shall set forth the amounts of payroll deductions, the Purchase Price, the number of Shares purchased and the remaining cash balance, if any.
- 12.9 No Employment Rights. Nothing in the Plan shall be construed to give any person (including any Eligible Employee or Participant) the right to remain in the employ of the Company or any Parent or Subsidiary or affect the right of the Company or any Parent or Subsidiary to terminate the employment of any person (including any Eligible Employee or Participant) at any time, with or without cause.
- 12.10 Notice of Disposition of Shares. Each Participant shall give prompt notice to the Company of any disposition or other transfer of any Shares purchased upon exercise of a right under the Plan if such disposition or transfer is made: (a) within two years from the Enrollment Date of the Offering Period in which the Shares were purchased or (b) within one year after the Purchase Date on which such Shares were purchased. Such notice shall specify the date of such disposition or other transfer and the amount realized, in cash, other property, assumption of indebtedness or other consideration, by the Participant in such disposition or other transfer.

- 12.11 <u>Governing Law</u>. The Plan and any agreements hereunder shall be administered, interpreted and enforced under the internal laws of the Cayman Islands without regard to conflicts of laws thereof or of any other jurisdiction.
- 12.12 <u>Electronic Forms</u>. To the extent permitted by Applicable Law and in the discretion of the Administrator, an Eligible Employee may submit any form or notice as set forth herein by means of an electronic form approved by the Administrator. Before the commencement of an Offering Period, the Administrator shall prescribe the time limits within which any such electronic form shall be submitted to the Administrator with respect to such Offering Period in order to be a valid election.

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### SUBSIDIARIES OF MEIRAGTX HOLDINGS PLC

Legal Name of SubsidiaryJurisdiction of OrganizationMeiraGTx LimitedEngland and Wales

MeiraGTx, LLC Delaware

MeiraGTx UK II Limited England and Wales

### **Consent of Independent Registered Public Accounting Firm**

We consent to the reference to our firm under the caption "Experts" and to the use of our report dated March 29, 2018 (except for Note 6, as to which the date is May 11, 2018) in Amendment No. 2 to the Registration Statement (Form S-1 No. 333-224914) and related Prospectus of MeiraGTx Holdings plc for the registration of its ordinary shares.

/s/ Ernst & Young LLP Stamford, Connecticut May 28, 2018