UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

Current Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **August 10, 2023**

MeiraGTx Holdings plc

(Exact name of registrant as specified in its charter)

Cayman Islands	**001-38520**	**98-1448305**
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S. Employer Identification No.)

450 East 29th Street, 14th Floor
New York, NY 10016
(Address of principal executive offices) (Zip code)

(646) 860-7985
(Registrant's telephone number, including area code)

Not applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Ordinary Shares, $0.00003881 par value per share	**MGTX**	**The Nasdaq Global Select Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 1.01. Entry Into a Material Definitive Agreement.

On August 10, 2023, MeiraGTx Holdings plc (the "Company"), as issuer, and its wholly-owned subsidiaries MeiraGTx UK II Limited, a company incorporated in England and Wales ("MeiraGTx UK II"), and MeiraGTx Ireland DAC, a designated activity company limited by shares incorporated in Ireland ("MeiraGTx Ireland," and together with MeiraGTx UK II, the "Subsidiary Guarantors"), entered into a Consent and Amendment to Amended and Restated Note Purchase Agreement and Guaranty (the "Consent and Amendment") by and among the Company, the Subsidiary Guarantors, the noteholders and other parties from time to time party thereto, and Perceptive Credit Holdings III, LP, as administrative agent and noteholder ("Perceptive"). The Consent and Amendment amends the Amended and Restated Note Purchase Agreement and Guaranty, dated December 19, 2022, between the Company, the Subsidiary Guarantors, the noteholders and other parties from time to time party thereto, and Perceptive (the "Note Purchase Agreement").

Under the Consent and Amendment, the Company may request in its sole discretion, and Perceptive has agreed to subscribe to purchase upon such request, an additional $25 million notes issuance (the "Tranche 2 Notes") at any time before August 2, 2024 subject to the terms of the Note Purchase Agreement. Previously, the Company's request for issuance of the Tranche 2 Notes was to be determined at Perceptive's sole discretion. The Note Purchase Agreement was also amended to increase the applicable early redemption fee (as defined and further described under the Consent and Amendment). The repayment terms for the Tranche 2 Notes are the same as those previously disclosed pursuant to the Note Purchase Agreement.

Ellen Hukkelhoven, Ph.D., a member of the Company's Board of Directors, is Head of Biotechnology Investments at Perceptive Advisors, LLC, an affiliate of Perceptive. Additionally, affiliates of Perceptive own, in the aggregate, more than 10% of the Company's outstanding shares.

The foregoing description of the Consent and Amendment does not purport to be complete and is qualified in its entirety by reference to the full text of the Consent and Amendment, a copy of which is attached as Exhibit 10.1 hereto and incorporated herein by reference.

Item 2.02. Results of Operations and Financial Condition.

On August 10, 2023, the Company issued a press release announcing its financial results for the quarter ended June 30, 2023. The full text of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this Item 2.02 and the accompanying Exhibit 99.1 shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section, nor shall it be deemed to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 2.03. Creation of a Direct Financial Obligation or an Obligation under an Off-Balance Sheet Arrangement of a Registrant.

The information set forth in Item 1.01 regarding the financial obligations under the Consent and Amendment and the Note Purchase Agreement is incorporated by reference into this Item 2.03.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
10.1	Consent and Amendment to Amended and Restated Note Purchase Agreement and Guaranty, dated August 10, 2023, by and among MeiraGTx Holdings plc, as issuer, the subsidiary guarantors and noteholders from time to time party thereto, and Perceptive Credit Holdings III, LP, as administrative agent and noteholder.
99.1	Press release of MeiraGTx Holdings plc, dated August 10, 2023.
104	Cover Page Interactive Data File (the cover page XBRL tags are embedded in the Inline XBRL document).

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: August 10, 2023

MEIRAGTX HOLDINGS PLC

By: /s/ Richard Giroux
Name: Richard Giroux
Title: Chief Financial Officer and Chief Operating Officer

Exhibit 10.1

Execution Version

CONSENT AND AMENDMENT TO AMENDED AND RESTATED NOTE PURCHASE AGREEMENT AND GUARANTY

This CONSENT AND AMENDMENT TO AMENDED AND RESTATED NOTE PURCHASE AGREEMENT AND GUARANTY, dated as of August 10, 2023 (this "***Agreement***"), is by and among MEIRAGTX HOLDINGS PLC, an exempted company with limited liability incorporated under the laws of the Cayman Islands with registration number 336306 (the "***Issuer***"), certain Subsidiaries of the Issuer party hereto (the "***Subsidiary Guarantors***"), the Noteholders party hereto, and PERCEPTIVE CREDIT HOLDINGS III, LP, as administrative agent for the Noteholders (in such capacity, together with its successors and assigns, the "***Administrative Agent***").

WHEREAS, the Issuer, the Subsidiary Guarantors, the Noteholders from time to time party thereto (the "***Noteholders***") and the Administrative Agent are parties to that certain Amended and Restated Note Purchase Agreement and Guaranty, dated as of December 19, 2022 (as amended, restated, supplemented or otherwise modified from time to time, the "***Note Purchase Agreement***"; capitalized terms used herein without definition shall have the same meanings as set forth in the Note Purchase Agreement as amended hereby);

WHEREAS, pursuant to Section 6.02 of the Note Purchase Agreement, the Issuer has requested that the Majority Noteholders commit to the subscription for the Tranche 2 Notes in an aggregate principal amount of $25,000,000 and the Majority Noteholders have agreed, subject to the terms and conditions of this Agreement, to consent to such commitment to subscribe to the Tranche 2 Notes; and

WHEREAS, the Issuer, the Administrative Agent and the Noteholders also desire to amend certain sections of the Note Purchase Agreement;

NOW THEREFORE, in consideration of the mutual covenants herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Issuer, the Subsidiary Guarantors, the Administrative Agent and the Noteholders agree as follows:

1. **Recitals.** The foregoing recitals are confirmed by Issuer as true and correct and are incorporated herein by reference.

2. **Consent and Amendments.** Effective as of the Effective Date, and in reliance on the representations and warranties of the Obligors in Section 4 below:

(a) Consent. Pursuant to Section 6.02 of the Note Purchase Agreement, the Majority Noteholders hereby consent (i) to the issuance by the Issuer of the Tranche 2 Notes and (ii) to subscribe to the purchase of such Tranche 2 Notes, in each case, during the Tranche 2 Notes Draw Period and subject to the terms and conditions set forth in the Note Purchase Agreement (including such conditions described in the second sentence of Section 6.02 of the Note Purchase Agreement)

(b) Amendments. The Note Purchase Agreement is hereby amended as follows:

(i) The definition of "Early Redemption Fee" set forth in Section 1.01 of the Note Purchase Agreement is hereby amended and restated in its entirety to read as follows:

"***Early Redemption Fee***" means, with respect to any redemption of all or any portion of the outstanding principal amount of the Notes on any Early Redemption Date, whether pursuant to **clause (a)** or **(b)** of **Section 3.03** or otherwise, occurring (i) on or prior to the first anniversary of the Closing Date, an amount equal to the sum of five and thirty-three hundredths percent (5.33%) of

the aggregate outstanding principal amount of the Notes being prepaid; (ii) at any time after the first anniversary of the Closing Date and on or prior to the second anniversary of the Closing Date, an amount equal to five and thirty-three hundredths percent (5.33%) of the aggregate outstanding principal amount of the Notes being redeemed; (iii) at any time after the second anniversary of the Closing Date and on or prior to the third anniversary of the Closing Date, an amount equal to one and thirty-three hundredths percent (1.33%) of the aggregate outstanding principal amount of the Notes being redeemed and (iv) thereafter, zero percent (0%) of the aggregate outstanding principal amount of the Notes being redeemed.

(ii) In the preamble of Section 9.02 of the Note Purchase Agreement, the words "now owned" are deleted and replaced in their entirety with the following text: "now or in the future owned".

The foregoing consents and amendments shall be limited as written and shall not be deemed or otherwise construed to constitute a waiver or forbearance of any other Default or Event of Default now existing or hereafter arising under the Notes Documents or constitute a course of conduct or dealing among the parties. Except for the consents and amendments expressly provided herein, the Noteholders and the Administrative Agent reserve all rights, privileges and remedies under the Note Purchase Agreement and the other Notes Documents.

3. **Conditions Precedent.** This Agreement shall become effective only upon, and shall be subject to, the prior or simultaneous satisfaction or waiver of each of the following conditions precedent in a manner reasonably satisfactory to the Administrative Agent (the date satisfaction of such conditions being referred to as the "***Effective Date***"):

(a) the Administrative Agent shall have received counterparts of this Agreement executed by each party thereto;

(b) the representations and warranties of the Obligors set forth in Section 4 below shall be true and correct as of the date hereof both immediately before and after giving effect to this Agreement; and

(c) the Administrative Agent and the Noteholders shall have received all fees, costs and expenses due and payable pursuant to Section 14.03 of the Note Purchase Agreement (including without limitation, the reasonable and documented fees and expenses of Morrison & Foerster LLP, counsel to the Administrative Agent and the Noteholders).

4. **Acknowledgment; Representations and Warranties.**

(a) Each Obligor confirms and agrees that, notwithstanding the effectiveness of this Agreement, the Obligations of such Obligor under each Notes Document to which such Obligor is a party shall not be impaired and each Notes Document to which such Obligor is a party is, and shall continue to be, in full force and effect and is hereby confirmed and ratified in all respects, except that upon the Effective Date, the terms, conditions, rights and remedies with respect to such Obligations of the Obligors shall be governed by the Note Purchase Agreement as amended hereby. Each Obligor hereby consents to the modifications made to the Note Purchase Agreement and hereby agrees that, upon the occurrence of the Effective Date, and except as otherwise expressly set forth herein, each Notes Document to which it is a party is and shall continue to be in full force and effect and the same are hereby ratified in all respects.

(b) Each Obligor hereby acknowledges and agrees that the Guaranteed Obligations will include all Obligations under, and as defined in, the Note Purchase Agreement as amended hereby. Each Obligor hereby ratifies, confirms and reaffirms all terms and conditions of all security and other

collateral granted to the Administrative Agent, and confirms that the indebtedness secured thereby includes, without limitation, the Obligations.

(c) To induce the Administrative Agent and the Noteholders party hereto to execute and deliver this Agreement, each Obligor party hereto represents and warrants to the Administrative Agent and the Noteholders party hereto that as of the date hereof, each of the following statements are true and correct:

(i) The representations and warranties made by each Obligor party hereto herein, in the Note Purchase Agreement and each other Notes Document are true and correct in all material respects as if made on and as of such date (or in the case of any representation or warranty qualified by materiality, Material Adverse Effect or similar qualification, true and correct in all respects) unless stated to relate solely to an earlier date, in which case such representations or warranties shall be true and correct in all material respects as of such earlier date.

(ii) The execution, delivery and performance of this Agreement by each Obligor party hereto, and the Note Purchase Agreement as amended hereby, have been duly authorized by all necessary corporate or other organizational action on the part of such Obligor, and each of this Agreement and the Note Purchase Agreement as amended hereby constitutes a legal, valid and binding agreement of such Obligor, enforceable against such Obligor in accordance with its respective terms, except as enforcement may be limited by (i) bankruptcy, insolvency, reorganization, moratorium or similar laws of general applicability affecting the enforcement of creditors' rights generally; (ii) general principles of equity (regardless of whether such enforceability is considered in a proceeding in equity or at law); and (iii) solely in respect of the English Guarantor and the Irish Subsidiary Guarantor, the Legal Reservations and the Perfection Requirements.

(iii) The execution, delivery and performance of this Agreement by any Obligor party hereto, and the resulting amendment to the Note Purchase Agreement, do not (i) violate or conflict with any Law, (ii) result in the creation or imposition of any Lien (other than Permitted Liens) on any asset of such Obligor or any of its Subsidiaries or (iii) violate, or result in a default under, any Material Agreement binding upon such Obligor or any of its Subsidiaries that, in the case of clause (i) and (iii) above, individually or in the aggregate, could reasonably be expected to result in a Material Adverse Effect.

(iv) No authorization or approval or other action by, and no notice or filing with, any Governmental Authority or any other Person (other than those that have been duly obtained or made and which are in full force and effect) is required for the due execution, delivery and performance by any Obligor party to this Agreement or the Note Purchase Agreement as amended hereby, other than any filing of this Agreement after the Effective Date with the applicable Recognised Stock Exchange as contemplated by Section 4(d).

(v) Immediately before and after giving effect to this Agreement, no event has occurred and is continuing that constitutes an Event of Default.

(d) Within thirty days of the Effective Date, the Issuer shall cause this Agreement to be filed with the Cayman Islands Stock Exchange as required by the rules and regulations thereof.

5. **Miscellaneous.**

(a) This Agreement may be executed in any number of duplicate originals or counterparts, each of such duplicate originals or counterparts shall be deemed to be an original and all taken together shall constitute but one and the same instrument. Delivery of an executed counterpart of the

signature page to this Agreement by electronic transmission shall be effective as delivery of a manually executed counterpart. Each party agrees that the other parties may rely on electronically delivered signatures of this Agreement by such party. Any signature (including, without limitation, (x) any electronic symbol or process attached to, or associated with, a contract or other record and adopted by a Person with the intent to sign, authenticate or accept such contract or record and (y) any facsimile transmission or PDF format signature) hereto or to any other certificate, agreement or document related to the transactions contemplated hereby, and any contract formation or record-keeping, in each case, through electronic means, shall have the same legal validity and enforceability as a manually executed signature or use of a paper-based record-keeping system to the fullest extent permitted by applicable law, including the Federal Electronic Signatures in Global and National Commerce Act, the New York State Electronic Signatures and Records Act, or any similar state law based on the Uniform Electronic Transactions Act, and the parties hereto hereby waive any objection to the contrary.

(b) This Agreement, together with the other Notes Documents, constitutes the entire agreement among the parties with respect to the subject matter hereof and supersedes any and all previous agreements and understanding, oral or written, relating to the subject matter hereof.

(c) This Agreement shall constitute a Notes Document executed pursuant to the Note Purchase Agreement and shall (unless otherwise expressly indicated therein) be construed, administered and applied in accordance with all the terms and provisions of the Note Purchase Agreement.

(d) This Agreement shall be binding upon and shall inure to the benefit of the parties hereto, their respective successors and permitted assigns.

(e) This Agreement and the rights and obligations of the parties hereunder shall be governed by, and construed in accordance with the law of the State of New York, without regard to principal of conflicts of law that would result in the application of the laws of any other jurisdiction; provided that Section 5-1401 of the New York General Obligations Law shall apply. The jurisdiction and waiver of jury trial provisions set forth in Sections 14.10 and 14.11 of the Note Purchase Agreement, respectively, are incorporated herein by reference mutatis mutandis.

[Signature Page Follows]

This Agreement has been executed and delivered by the parties by their authorized officers on the date first above written.

ISSUER:

MEIRAGTX HOLDINGS PLC

By /s/ Richard Giroux
Name: Richard Giroux
Title: Chief Financial Officer and Chief Operating Officer

SUBSIDIARY GUARANTORS:

MEIRAGTX UK II LIMITED

By /s/ Richard Giroux
Name: Richard Giroux
Title: Chief Financial Officer and Chief Operating Officer

MEIRAGTX IRELAND DAC

By /s/ Richard Giroux
Name: Richard Giroux
Title: Chief Financial Officer and Chief Operating Officer

PERCEPTIVE CREDIT HOLDINGS III, LP, as the Administrative Agent and Noteholder

By: PERCEPTIVE CREDIT OPPORTUNITIES GP, LLC**,** its general partner

By /s/ Sandeep Dixit
Name: Sandeep Dixit
Title: Chief Credit Officer

By /s/ Sam Chawla
Name: Sam Chawla
Title: Portfolio Manager

Exhibit 99.1

MeiraGTx Reports Second Quarter 2023 Financial and Operational Results

- *Phase 3 LUMEOS clinical trial of botaretigene sparoparvovec (bota-vec, formerly AAV-RPGR) for the treatment of X-linked retinitis pigmentosa (XLRP) enrollment target has now been surpassed*

- *Announced positive clinical data from the completed AQUAx Phase 1 study of AAV2-hAQP1 for the treatment of grade 2/3 radiation-induced xerostomia (RIX), showing bilaterally treated participants reaching normal levels of whole saliva flow rate by 2 months post-treatment and persisting through the final Month 12 assessment in the study*

- *Initiated Phase 2 randomized, double-blind, placebo-controlled study of AAV2-hAQP1 for the treatment of grade 2/3 RIX*

- *Wholly-owned gene therapy manufacturing facility in Shannon, Ireland received Commercial MIA Authorization for QC Testing and is the first manufacturing site for gene therapy to receive a commercial license in Ireland*

- *Presented data on proprietary RiboCAR platform demonstrating improved CAR-T anti-cancer efficacy and durability at the 2023 American Society of Gene and Cell Therapy (ASGCT) Spotlight on Immuno-Oncology*

LONDON and NEW YORK, August 10, 2023 (GLOBE NEWSWIRE) -- MeiraGTx Holdings plc (Nasdaq: MGTX), a vertically integrated, clinical stage gene therapy company, today announced financial and operational results for the second quarter ended June 30, 2023, and provided a corporate update.

“Progress across our programs and infrastructure continues to be extremely impressive,” said Alexandria Forbes, Ph.D., president and chief executive officer of MeiraGTx. “This includes further advancement of our three lead clinical programs, our riboswitch gene regulation technology platform, and our manufacturing platform. This quarter, we announced positive data from the completed AQUAx Phase 1 study, demonstrating clinically meaningful improvements in long term xerostomia patients, and we are currently enrolling and treating patients in our Phase 2 trial. In the Phase 3 LUMEOS trial of bota-vec for the treatment of XLRP, we have now surpassed the enrollment target and expect a BLA submission next year. In addition, we presented unprecedented preclinical data from our novel gene regulation platform at the ASGCT Annual and ASGCT Spotlight on Immuno-oncology meetings. We are particularly excited by our groundbreaking RiboCAR technology. RiboCAR enables precise and reversible regulation of CAR expression in response to small molecule inducers, with the regulated CAR-T showing increased activity and durability compared to CAR-T with constitutively active CAR, as well as significant implications for safety. We are excited to continue this work with leaders in the field in moving RiboCAR towards the clinic, particularly in the treatment of solid tumors where we believe RiboCAR’s benefits have the potential to transform patient outcomes.”

Dr. Forbes continued, “We continue to build on our unique end-to-end manufacturing capabilities with a commercial QC testing license for our state-of-the-art manufacturing facility in Shannon, Ireland. This is the first commercial license for a gene therapy facility in Ireland. This authorization allows us to accelerate the development of our pipeline and serve as a reliable QC testing facility for advanced therapies on a global scale, and provides the opportunity to add additional revenue from potential partners.”

Recent Development Highlights and Anticipated Milestones

Bota-vec for the Treatment of XLRP:

- Enrollment target in the pivotal Phase 3 LUMEOS clinical trial of bota-vec has been surpassed, with BLA submission expected in 2024.
- In late April, immune-response data from a Phase 1/2 MGT009 clinical trial (NCT03252847) were presented at the Association for Research in Vision and Ophthalmology (ARVO) 2023 Annual Meeting.

AAV-hAQP1 for the Treatment of Grade 2/3 Radiation-Induced Xerostomia:

- Initiated a Phase 2 randomized, double-blind, placebo-controlled study with participants currently being enrolled and dosed.
- Reported clinically meaningful improvements from the AQUAx Phase 1 study in xerostomia symptoms measured by two different xerostomia patient reported outcome questionnaires (PROs) demonstrated across both unilaterally and bilaterally treated cohorts at 12 months:
    - Increases in whole saliva flow rates observed post-treatment, providing objective evidence of biological activity, reaching the normal range in bilaterally treated participants by 2 months and persisting through the Month 12 assessment.
    - Across assessments, greater improvements were observed in bilaterally treated participants compared to those treated unilaterally.
    - Early long-term follow-up data suggest durability of improvement to at least 3 years post-treatment.
    - AAV2-hAQP1 appears safe and well tolerated at each dose tested.
    - The strong safety and encouraging, clinically meaningful activity data support further clinical development of AAV2-hAQP1.
- The Company anticipates presenting the full data from the AQUAx Phase 1 study at the next appropriate medical meeting.

Wholly-Owned Gene Therapy Manufacturing Facility in Shannon, Ireland has Received Commercial MIA Authorization for QC Testing

- The QC facility in Shannon, Ireland performs advanced biochemical quality control testing for release and stability testing for MeiraGTx’s and its partner’s programs.
- Unique in its scale and integrated capabilities and stretching over 150,000 square feet, the GMP Shannon facility is Ireland’s first commercial-scale gene therapy manufacturing site and contains facilities for flexible and scalable viral vector production for clinical and commercial supply as well as a facility for plasmid DNA production in addition to the GMP licensed QC facility.

AAV-GAD for the Treatment of Parkinson's Disease:

- The Company is dosing patients in the AAV-GAD clinical trial under a new IND with material manufactured in its cGMP facility in London, United Kingdom using MeiraGTx's proprietary production process.
- The AAV-GAD trial is a three arm randomized Phase 1 clinical bridging study with subjects randomized to sham control or one of two doses of AAV-GAD.
- The objective of the AAV-GAD trial (NCT05603312) is to evaluate the safety and tolerability of AAV-GAD manufactured at MeiraGTx's cGMP facility in London, United Kingdom when delivered to the subthalamic nucleus (STN) of patients with Parkinson's disease.
- Completion of enrollment is anticipated in the third quarter of 2023.

Riboswitch Gene Regulation Platform & Vector Engineering:

- Presented data at the 2023 ASGCT Spotlight on Immuno-Oncology
  - RiboCAR-T cell activity can be precisely tuned and "remotely" controlled to improve the efficacy, durability, and safety of CAR-T cell therapy.
  - Proprietary switch allows the Company to precisely and reversibly control the expression of CAR in a dose-response to novel small molecule inducers to unprecedented levels, from undetectable at baseline to at least as high as levels of constitutively expressed CAR driven by the small molecule dose.
- Presentations at the ASGCT 2023 Annual Meeting
  - The Company exhibited nine poster presentations highlighting the depth and novelty of MeiraGTx's technology platforms for gene and cell therapy.

For more information related to our clinical trials, please visit www.clinicaltrials.gov

As of June 30, 2023, MeiraGTx had cash and cash equivalents of approximately $92.8 million, as well as approximately $32.7 million in receivables due from Janssen. The Company believes that with such funds, as well as anticipated milestones from Janssen, it will have sufficient capital to fund operating expenses and capital expenditure requirements into the second quarter of 2025.

Financial Results

Cash and cash equivalents were $92.8 million as of June 30, 2023, compared to $115.5 million as of December 31, 2022.

License revenue was $3.5 million for the quarter ended June 30, 2023, compared to $10.8 million for the quarter ended June 30, 2022. This decrease represents decreased amortization of the $100.0 million upfront payment as well as decreased amortization of the $30.0 million milestone payment received in connection with the Janssen collaboration.

General and administrative expenses were $12.4 million for the three months ended June 30, 2023, compared to $10.5 million for the three months ended June 30, 2022. The increase of $1.9 million was primarily due to an increase in legal and accounting fees, payroll and payroll-related

costs, share-based compensation and other office related costs. These increases were partially offset by decreases in insurance costs and consulting fees.

Research and development expenses for the three months ended June 30, 2023, were $19.9 million, compared to $24.0 million for the three months ended June 30, 2022. The decrease of $4.1 million was primarily due to a decrease in expenses related to our preclinical programs primarily due to the timing of expenses in our gene regulation program, manufacturing costs related to lower production volumes, other research and development expenses primarily due to a decrease in share-based compensation, and an increase in research funding provided under our Janssen collaboration primarily due to the increase in expenses incurred related to our program for bota-vec for the treatment of XLRP. These decreases were partially offset by an increase in clinical trial expenses primarily due to an increase in expenses related to our Phase 3 LUMEOS clinical trial of bota-vec and our expanded Phase 1 clinical trial and our Phase 2 clinical trial for AAV-hAQP1.

Foreign currency gain was $1.9 million for the three months ended June 30, 2023, compared to a loss of $10.4 million for the three months ended June 30, 2022. The change of $12.3 million was primarily due to an unrealized gain on the quarterly valuation of intercompany payables and receivables due to the weakening of the U.S. dollar against the pound sterling and euro during the three months ended June 30, 2023.

Net loss attributable to ordinary shareholders for the quarter ended June 30, 2023 was $29.6 million, or $0.53 basic and diluted net loss per ordinary share, compared to a net loss attributable to ordinary shareholders of $34.0 million, or $0.76 basic and diluted net loss per ordinary share for the quarter ended June 30, 2022.

About MeiraGTx
MeiraGTx (Nasdaq: MGTX) is a vertically integrated, clinical-stage gene therapy company with six programs in clinical development and a broad pipeline of preclinical and research programs. MeiraGTx has core capabilities in viral vector design and optimization and gene therapy manufacturing, and a transformative gene regulation platform technology that allows precise, dose responsive control of gene expression by oral small molecules with dynamic range that can exceed 5000-fold. Led by an experienced management team, MeiraGTx has taken a portfolio approach by licensing, acquiring, and developing technologies that give depth across both product candidates and indications. MeiraGTx's initial focus is on three distinct areas of unmet medical need: ocular diseases, including both inherited retinal diseases as well as large degenerative ocular diseases, neurodegenerative diseases and severe forms of xerostomia. Though initially focusing on the eye, central nervous system, and salivary gland, MeiraGTx plans to expand its focus to develop additional gene therapy treatments for patients suffering from a range of serious diseases.

For more information, please visit www.meiragtx.com

Forward Looking Statement
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements,

including, without limitation, statements regarding our product candidate development and anticipated milestones regarding our pre-clinical and clinical data, reporting of such data and the timing of results of data and regulatory matters, as well as statements that include the words “expect,” “will,” “intend,” “plan,” “believe,” “project,” “forecast,” “estimate,” “may,” “could,” “should,” “would,” “continue,” “anticipate” and similar statements of a future or forward-looking nature. These forward-looking statements are based on management’s current expectations. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, our incurrence of significant losses; any inability to achieve or maintain profitability, raise additional capital, repay our debt obligations, identify additional and develop existing product candidates, successfully execute strategic priorities, bring product candidates to market, expansion of our manufacturing facilities and processes, successfully enroll patients in and complete clinical trials, accurately predict growth assumptions, recognize benefits of any orphan drug designations, retain key personnel or attract qualified employees, or incur expected levels of operating expenses; the impact of the COVID-19 pandemic on the status, enrollment, timing and results of our clinical trials and on our business, results of operations and financial condition; failure of early data to predict eventual outcomes; failure to obtain FDA or other regulatory approval for product candidates within expected time frames or at all; the novel nature and impact of negative public opinion of gene therapy; failure to comply with ongoing regulatory obligations; contamination or shortage of raw materials or other manufacturing issues; changes in healthcare laws; risks associated with our international operations; significant competition in the pharmaceutical and biotechnology industries; dependence on third parties; risks related to intellectual property; changes in tax policy or treatment; our ability to utilize our loss and tax credit carryforwards; litigation risks; and the other important factors discussed under the caption “Risk Factors” in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2023, as such factors may be updated from time to time in our other filings with the SEC, which are accessible on the SEC’s website at www.sec.gov. These and other important factors could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Any such forward-looking statements represent management’s estimates as of the date of this press release. While we may elect to update such forward-looking statements at some point in the future, unless required by law, we disclaim any obligation to do so, even if subsequent events cause our views to change. Thus, one should not assume that our silence over time means that actual events are bearing out as expressed or implied in such forward-looking statements. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this press release.

Contacts

Investors:
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or

Media:
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LifeSci Communications
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MEIRAGTX HOLDINGS PLC AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(unaudited)
(in thousands, except share and per share amounts)

	For the Three-Month Period Ended June 30,		For the Six-Month Period Ended June 30,	
	2023	2022	2023	2022
License revenue - related party	$ 3,540	$ 10,759	$ 6,874	$ 16,392
Operating expenses:				
General and administrative	12,388	10,518	25,160	21,786
Research and development	19,937	23,999	42,259	47,098
Total operating expenses	32,325	34,517	67,419	68,884
Loss from operations	(28,785)	(23,758)	(60,545)	(52,492)
Other non-operating income (expense):				
Foreign currency gain (loss)	1,905	(10,426)	5,762	(13,073)
Interest income	655	41	1,200	57
Interest expense	(3,355)	(82)	(6,415)	(159)
Fair value adjustment	(1)	252	53	649
Net loss	(29,581)	(33,973)	(59,945)	(65,018)
Other comprehensive (loss) income:				
Foreign currency translation (loss) gain	(2,541)	7,357	(4,894)	9,290
Comprehensive loss	$ (32,122)	$ (26,616)	$ (64,839)	$ (55,728)
Net loss	$ (29,581)	$ (33,973)	$ (59,945)	$ (65,018)
Basic and diluted net loss per ordinary share	$ (0.53)	$ (0.76)	$ (1.15)	$ (1.46)
Weighted-average number of ordinary shares outstanding	55,349,534	44,668,240	52,012,382	44,585,239

MEIRAGTX HOLDINGS PLC AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited)
(in thousands, except share and per share amounts)

	June 30, 2023	December 31, 2022
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 92,773	$ 115,516
Accounts receivable - related party	32,690	21,334
Prepaid expenses	8,108	8,133
Tax incentive receivable	8,026	7,689
Other current assets	1,547	1,667
Total Current Assets	143,144	154,339
Property, plant and equipment, net	114,004	109,266
Intangible assets, net	1,252	1,335
In-process research and development	753	742
Other assets	1,465	1,402
Equity method and other investments	6,326	6,326
Right-of-use assets - operating leases, net	18,693	20,109
Right-of-use assets - finance leases, net	24,626	24,718
TOTAL ASSETS	$ 310,263	$ 318,237
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 28,497	$ 16,616
Accrued expenses	24,889	39,818
Lease obligations, current	4,126	3,884
Deferred revenue - related party, current	12,058	15,123
Other current liabilities	2,233	6,631
Total Current Liabilities	71,803	82,072
Deferred revenue - related party	25,364	27,436
Lease obligations	15,508	17,331
Asset retirement obligations	2,301	2,179
Deferred income tax liability	189	186
Note payable, net	71,571	71,033
Other long-term liabilities	—	262
TOTAL LIABILITIES	186,736	200,499
COMMITMENTS AND CONTINGENCIES (Note 10)		
SHAREHOLDERS' EQUITY:		
Ordinary Shares, $0.00003881 par value, 1,288,327,750 authorized, 59,535,314 and 48,477,209 shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively	2	2
Capital in excess of par value	652,521	581,893
Accumulated other comprehensive income	1,153	6,047
Accumulated deficit	(530,149)	(470,204)
Total Shareholders' Equity	123,527	117,738
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 310,263	$ 318,237