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 8, 2018

MeiraGTx Holdings plc
(Exact name of registrant as specified in its charter)

Cayman Islands	**001-38520**	**Not applicable**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

430 East 29th Street, 10th Floor
New York, NY 10016
(Address of principal executive offices) (Zip code)

(425) 783-3616
(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))

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 2.02. Results of Operations and Financial Condition.

On August 8, 2018, MeiraGTx Holdings plc (the "Company") issued a press release announcing its financial results for the quarter ended June 30, 2018. 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 Current Report on Form 8-K (including 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, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release of MeiraGTx Holdings plc, dated August 8, 2018

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 8, 2018

MEIRAGTX HOLDINGS PLC

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

MeiraGTx Reports Second Quarter 2018 Financial Results and Provides Corporate Update

LONDON and NEW YORK, August 8, 2018 (GLOBE NEWSWIRE) — MeiraGTx Holdings Plc (NASDAQ:MGTX), a vertically integrated, clinical stage gene therapy company, today announced financial results for the second quarter of 2018 and provided a corporate update.

“This has been an important year and an exciting time for MeiraGTx. We completed our initial public offering in June of this year and strengthened our track record of strong execution,” said Alexandria Forbes, Ph.D., President and Chief Executive Officer of MeiraGTx. “While continuing to advance our clinical programs this past quarter, we also achieved important regulatory milestones, including Fast Track designation from the FDA for our AAV-RPGR program for the treatment of X-linked retinitis pigmentosa due to *RPGR* deficiency and receipt of a positive opinion for orphan drug designation from the EMA for our AAV-CNGA3 therapy for the treatment of achromatopsia. I am proud of all we have accomplished to date and am grateful to the entire MeiraGTx team for their efforts as we continue to work to improve the lives of patients suffering from devastating diseases.”

Clinical Development Highlights

AAV-CNGB3: Completed the dose escalation phase of the treatment study, with 11 adult patients treated in the three dose escalation cohorts. In addition, 3 pediatric patients have now been treated in the extension phase of the study. The Company anticipates completing dosing of up to 8 pediatric patients in 2H 2018.

AAV-RPGR: Completed dosing of the second dose escalation cohort, bringing the total number treated to 7 patients. The independent data monitoring committee, or IDMC, has recommended moving to the third and highest dose cohort and the Company anticipates completing dosing in this final adult cohort in Q3 2018. MeiraGTx expects to initiate dosing in the pediatric extension phase of the study in Q4 2018.

AAV-RPE65: Completed dosing in the Phase 1/2 clinical study. A total of 9 adults were treated in 3 escalating dose cohorts. 6 pediatric patients were treated in the pediatric extension arm of the study.

AAV-CNGA3: cGMP manufacturing of clinical material is ongoing in the Company’s manufacturing facility. The Company anticipates release at the end of 2018 with the initiation of the treatment study in early 2019.

Natural History Studies: MeiraGTx continues to enroll patients in the achromatopsia, XLRP and RPE65 long term natural history studies in Europe and the US, and in long-term follow-up studies in each indication.

Regulatory Highlights

Received Positive Opinion for Orphan Drug Designation from EMA for Achromatopsia Treatment: On June 26, 2018, the European Medicines Agency's (EMA) Committee for Orphan Medicinal Products issued a positive opinion recommending orphan Medicinal product (orphan drug) designation of MeiraGTx's AAV-CNGA3 for the treatment of achromatopsia caused by mutations in the *CNGA3* gene. The Company continues to work with the EMA to advance the clinical development of AAV-CNGA3.

Received Fast Track Designation from FDA for X-Linked Retinitis Pigmentosa Treatment: On April 23, 2018, the U.S. Food and Drug Administration (FDA) granted Fast Track designation for AAV-RPGR for the treatment of X-linked retinitis pigmentosa (XLRP) due to defects in the retinitis pigmentosa GTPase regulator (*RPGR*) gene. The Company is currently conducting an open label, Phase 1/2 dose escalation clinical trial of AAV-RPGR in adult and pediatric patients diagnosed with XLRP caused by mutations in the eye-specific form of the *RPGR* gene called RPGR open reading frame 15.

Granted MIA (IMP) License for UK cGMP Manufacturing Facility: On June 21, 2018, MeiraGTx was granted a Manufacturer's Authorization for Investigational Medicinal Products from the UK's Medicines and Healthcare products Regulatory Agency (MHRA), allowing the Company to manufacture gene therapy product candidates in its current cGMP compliant manufacturing facility. MeiraGTx's 29,000 square-foot facility located in central London was designed to operate as a flexible and scalable manufacturing hub, housing two cell production suites and three separate viral vector production suites, offering production of multiple product candidates in parallel, as well as sequentially at difference scales.

Corporate Highlights

Completed Initial Public Offering: In June 2018, MeiraGTx completed an initial public offering of 5,000,000 ordinary shares of common stock at a public offering price of $15.00 per share, raising net proceeds of $65.9 million, after underwriting discounts and commissions.

Second Quarter 2018 Financial Results

Three Months Ended June 30, 2018 and 2017

General and administrative expenses for the three months ended June 30, 2018 were $17.4 million, compared to $2.2 million for the same period in 2017. The $15.2 million increase was primarily attributable to increases in payroll and stock-based compensation, consultant and operational costs, which was partially offset by a decrease in rent and depreciation expenses.

Research and development expenses for the three months ended June 30, 2018 were $7.8 million, compared to $5.4 million for the same period in 2017. The $2.4 million increase was primarily attributable to an increase in costs related to the preparation of MeiraGTx's manufacturing facility for production and stock-based compensation, which was partially offset by a decrease in clinical trial material costs.

Foreign currency loss was $2.7 million for the three months ended June 30, 2018, compared to a gain of $0.5 million for the same period in 2017. The increase of $3.2 million was primarily attributable to a strengthening U.S. dollar against the pound sterling during the three months ended June 30, 2018.

Net loss for the three months ended June 30, 2018 was $30 million, or $(2.29) basic and diluted net loss per ordinary share, compared to a net loss of $7.2 million, or $(0.85) basic and diluted net loss per ordinary share for the three months ended June 30, 2017.

MeiraGTx ended the second quarter of 2018 with $102.1 million in cash and cash equivalents, compared to $8.5 million as of December 31, 2017.

About MeiraGTx

MeiraGTx (NASDAQ:MGTX) is a vertically integrated, clinical stage gene therapy company with four ongoing clinical programs and a broad pipeline of preclinical and research programs. MeiraGTx has 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, 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: inherited retinal diseases, severe forms of xerostomia and neurodegenerative diseases. Though initially focusing on the eye, salivary gland and central nervous system, MeiraGTx intends to expand its focus in the future 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 Statements

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 product pipeline, anticipated product benefits, goals and strategic priorities, product candidate development, growth expectations or targets and pre-clinical and clinical data, as well as statements that include the words "expect," "intend," "plan," "believe," "project," "forecast," "estimate," "may," "should," "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, acquire additional capital, identify additional and develop existing product candidates, continue operating as a going concern, successfully execute strategic priorities, bring product candidates to market, build-out the manufacturing facility 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; 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; 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; litigation risks; and the other important factors discussed under the caption "Risk Factors" in our final prospectus under Rule 424(b) filed with the U.S. Securities and Exchange Commission ("SEC") in connection with our initial public offering 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.

MEIRAGTX HOLDINGS PLC AND SUBSIDIARIES
CONDESNSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(unaudited)

	For the Three-Month Period Ended June 30,		For the Six-Month Period Ended June 30,	
	2018	2017	2018	2017
Operating expenses:				
General and administrative	$ 17,378,052	$ 2,221,896	$ 28,500,068	$ 4,370,436
Research and development	7,790,694	5,363,545	14,718,016	10,186,902
Total operating expenses	25,168,746	7,585,441	43,218,084	14,557,338
Loss from operations	(25,168,746)	(7,585,441)	(43,218,084)	(14,557,338)
Other non-operating income (expense):				
Other income	83,075	—	83,075	—
Foreign currency (loss) gain	(2,726,624)	449,625	(1,748,000)	598,874
Change in fair value of warrant liability	(2,184,183)	—	(1,514,775)	—
Interest income	25,354	7,991	50,662	18,380
Interest expense	(9,708)	(50,894)	(37,063)	(59,020)
Net loss	(29,980,832)	(7,178,719)	(46,384,185)	(13,999,104)
Other comprehensive income (loss)	1,979,007	(345,019)	1,221,242	(475,914)
Comprehensive loss	$ (28,001,825)	$ (7,523,738)	$ (45,162,943)	$ (14,475,018)
Net loss	$ (29,980,832)	$ (7,178,719)	$ (46,384,185)	$ (13,999,104)
Accretion on convertible preferred C shares and warrants	(1,141,794)	(30,401)	(1,806,512)	(53,162)
Adjusted net loss	$ (31,122,626)	$ (7,209,120)	$ (48,190,697)	$ (14,052,266)
Basic and diluted net loss per ordinary share	$ (2.29)	$ (0.85)	$ (4.27)	$ (1.64)
Weighted-average number of ordinary shares outstanding	13,611,452	8,505,149	11,280,804	8,545,437

See Notes to Condensed Consolidated Financial Statements

MEIRAGTX HOLDINGS PLC AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS

	June 30, 2018 (unaudited)	December 31, 2017
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 102,060,551	$ 8,548,638
Prepaid expenses	1,613,955	1,961,243
Other current assets	311,283	965,233
Total Current Assets	103,985,789	11,475,114
Property and equipment, net	13,567,806	14,255,729
Restricted cash	123,376	123,376
TOTAL ASSETS	$ 117,676,971	$ 25,854,219
LIABILITIES, CONVERTIBLE PREFERRED C SHARES AND SHAREHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES:		
Accounts payable	$ 3,461,441	$ 7,055,380
Accrued expenses	5,289,261	9,332,944
Note payable	—	1,442,009
Warrant liability	—	2,679,633
Capitalized lease obligation - current portion	28,715	30,850
Due to Kadmon	—	861,030
Total Current Liabilities	8,779,417	21,401,846
Capitalized lease obligation	20,732	34,298
Deferred rent	224,367	266,290
Other liabilities	180,350	178,419
TOTAL LIABILITIES	9,204,866	21,880,853
COMMITMENTS		
CONVERTIBLE PREFERRED C SHARES		
Convertible Preferred C Shares 0 and 5,005,935 outstanding at June 30, 2018 December 31, 2017, respectively (liquidation preference of $52,455,700 at December 31, 2017)	—	51,338,631
SHAREHOLDERS' EQUITY (DEFICIT):		
A Ordinary Shares, $0.00003881 nominal value 27,184,132 issued and outstanding at June 30, 2018 8,826,190 issued and 8,714,563 issued and outstanding at December 31, 2017	1,055	342
Capital in excess of nominal value	221,080,313	20,080,713
Accumulated other comprehensive loss	(801,235)	(2,022,477)
Accumulated deficit	(111,808,028)	(65,423,843)
Total Shareholders' Equity (Deficit)	108,472,105	(47,365,265)
TOTAL LIABILITIES, CONVERTIBLE PREFERRED C SHARES AND SHAREHOLDERS' EQUITY (DEFICIT)	$ 117,676,971	$ 25,854,219

See Notes to Condensed Consolidated Financial Statements

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