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): **May 7, 2020**

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.)

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 2.02. Results of Operations and Financial Condition.

On May 7, 2020 MeiraGTx Holdings plc (the "Company") issued a press release announcing its financial results for the quarter ended March 31, 2020. 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 May 7, 2020.

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: May 7, 2020

MEIRAGTX HOLDINGS PLC

By: /s/ Richard Giroux

Name: Richard Giroux

Title: Chief Financial Officer and Chief Operating Officer

Exhibit 99.1

MeiraGTx Reports First Quarter 2020 Financial Results

LONDON and NEW YORK, May 7, 2020 (GLOBE NEWSWIRE) -- MeiraGTx Holdings plc (Nasdaq: MGTX), a vertically integrated, clinical stage gene therapy company, today announced financial results for the first quarter ended March 31, 2020 and provided an update on recent progress.

During the first quarter of 2020, MeiraGTx remained focused on achieving its most important priorities for patients, including advancing its inherited retinal disease programs, progressing its xerostomia program through ongoing clinical studies, preparing for the next clinical trial of AAV-GAD for Parkinson's disease and planning the buildout of its second viral vector and plasmid manufacturing facility. In response to the COVID-19 pandemic, the Company is working closely with its development partners and clinical sites to implement solutions enabling continuity of study conduct while protecting the health and safety of employees, patients and healthcare providers.

"Our teams in the UK, U.S. and Netherlands are working tirelessly to minimize the disruption caused by the global COVID-19 pandemic and continue our mission of improving the lives of people with serious diseases," said Alexandria Forbes, Ph.D., president and chief executive officer of MeiraGTx. "Thank you to the MeiraGTx team and our collaborators for their dedication and commitment to developing transformative medicines during this challenging time."

As of March 31, 2020, MeiraGTx had cash, cash equivalents and restricted cash of approximately $211 million. The Company believes this capital will be sufficient to fund operating expenses and capital expenditure requirements into 2022.

Inherited Retinal Disease (IRD) Portfolio:

- MeiraGTx remains on track to report data from the ongoing Phase 1/2 clinical trial of AAV-RPGR for the treatment of X-linked retinitis pigmentosa in 2020, and continues to engage with global regulatory authorities as anticipated to advance the Company's IRD programs.

AAV-AQP1 for the treatment of Grade 2/3 Radiation-Induced Xerostomia:

- Patients who have been treated in MeiraGTx's Phase 1/2 AQUAx trial are continuing post-treatment follow-up assessments. The Company anticipates that treatment of new patients will resume in the second quarter of 2020. MeiraGTx expects to report preliminary clinical data from this trial in the second half of 2020.

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

- MeiraGTx has initiated the process for cGMP-grade AAV-GAD material and expects to file an Investigational New Drug (IND) application in late 2020 or early 2021.

Manufacturing and Supply Chain:

- MeiraGTx continues to anticipate that its cGMP plasmid production facility will be operational by the end of 2020, and that its second cGMP viral vector manufacturing facility will be operational in 2021.
- The Company has not experienced COVID-19 related supply chain disruptions and does not anticipate encountering supply chain disruptions that will impact its ability to support its current manufacturing and clinical trial activities.

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

Financial Results

Cash, cash equivalents and restricted cash were $210.8 million as of March 31, 2020, compared to $227.4 million as of March 31, 2019.

License revenue was $4.2 million for the quarter ended March 31, 2020, compared to $0.8 million for the quarter ended March 31, 2019. The increase represents increased amortization of the $100.0 million upfront payment that the Company received in March 2019 from its collaboration agreement with Janssen Pharmaceuticals, Inc. (Janssen), one of the Janssen Pharmaceutical Companies of Johnson & Johnson.

Research and development expenses were $8.1 million for the quarter ended March 31, 2020, compared to $13.0 million for the quarter ended March 31, 2019. The decrease of $4.9 million was primarily due to an increase in research funding under the Janssen collaboration agreement in the amount of $12.7 million, which was partially offset by increases in costs related to the manufacture of material for clinical trials and costs related to clinical trials.

General and administrative expenses were $11.8 million for the quarter ended March 31, 2020, compared to $8.5 million for the quarter ended March 31, 2019. The increase of $3.3 million was primarily due to increases in share-based compensation, payroll and payroll related costs, insurance costs and rent and facilities costs, which was partially offset by a decrease in legal and consulting fees.

Foreign currency loss was $0.8 million for the quarter ended March 31, 2020, compared to a gain of $2.7 million for the quarter ended March 31, 2019. The decrease of $3.5 million was primarily due to a strengthening of the U.S. dollar against the pound sterling during the quarter ended March 31, 2020.

Net loss attributable to ordinary shareholders for the quarter ended March 31, 2020 was $15.7 million, or $0.43 basic and diluted net loss per ordinary share, compared to a net loss attributable to ordinary shareholders of $18.0 million, or $0.62 basic and diluted net loss per ordinary share for the quarter ended March 31, 2019.

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, 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, neurodegenerative diseases and severe forms of xerostomia. Though initially focusing on the eye, central nervous system and salivary gland, 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 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 2020 milestones regarding our pre-clinical and clinical data and reporting of such data and the timing of results of data, including in light of the COVID-19 pandemic, 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, 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

March 31, 2020, 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.

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MEIRAGTX HOLDINGS PLC AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited)

	March 31, 2020	December 31, 2019
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 210,409,650	$ 227,233,384
Restricted cash	377,598	—
Accounts receivable - related party	27,979,259	23,337,377
Prepaid expenses	3,460,056	4,464,085
Tax incentive receivable	6,819,851	11,974,437
Other current assets	1,965,752	1,970,585
Total Current Assets	251,012,166	268,979,868
Property and equipment, net	25,430,812	23,858,108
Security deposits	709,886	951,138
In-process research and development	762,285	777,655
Restricted cash	—	123,376
Other assets	191,198	195,053
Right-of-use assets	26,561,496	29,002,448
TOTAL ASSETS	$ 304,667,843	$ 323,887,646
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 7,288,347	$ 3,759,339
Accrued expenses	12,784,394	18,083,757
Lease obligations, current	1,962,363	1,674,210
Deferred revenue - related party, current	20,930,133	25,678,515
Other current liabilities	60,780	—
Total Current Liabilities	43,026,017	49,195,821
Deferred revenue - related party	55,700,543	60,535,576
Lease obligations	19,172,729	21,504,340
Asset retirement obligations	1,652,570	1,654,755
Deferred income tax liability	191,198	195,053
TOTAL LIABILITIES	119,743,057	133,085,545
COMMITMENTS		
SHAREHOLDERS' EQUITY:		
Ordinary Shares, $0.00003881 par value, 1,288,327,750 authorized, 36,817,916 and 36,791,906 shares issued and outstanding at March 31, 2020 and December 31, 2019, respectively	1,430	1,429
Capital in excess of par value	401,488,623	395,630,666
Accumulated other comprehensive income (loss)	2,151,882	(1,794,042)
Accumulated deficit	(218,717,149)	(203,035,952)
Total Shareholders' Equity	184,924,786	190,802,101
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 304,667,843	$ 323,887,646

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

	For the Three Months Ended March 31,	
	2020	2019
License revenue - related party	$ 4,209,576	$ 784,960
Operating expenses:		
General and administrative	11,806,134	8,499,475
Research and development	8,083,342	12,976,229
Total operating expenses	19,889,476	21,475,704
Loss from operations	(15,679,900)	(20,690,744)
Other non-operating income (expense):		
Foreign currency (loss) gain	(756,701)	2,718,400
Interest income	789,370	—
Interest expense	(33,966)	(9,574)
Net loss	(15,681,197)	(17,981,918)
Other comprehensive income (loss):		
Foreign currency translation gain (loss)	3,945,924	(1,133,683)
Total comprehensive loss	$ (11,735,273)	$ (19,115,601)
Basic and diluted net loss per ordinary share	$ (0.43)	$ (0.62)
Weighted-average number of ordinary shares outstanding	36,624,950	28,776,915