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): **March 11, 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 pur Section 13(a) of the Exchange Act. ☐

Item 2.02. Results of Operations and Financial Condition.

On March 11, 2020 MeiraGTx Holdings plc (the "Company") issued a press release announcing its financial results for the year ended December 31, 2019. 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 March 11, 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: March 11, 2020

MEIRAGTX HOLDINGS PLC

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

MeiraGTx Reports Full Year 2019 Financial Results

LONDON and NEW YORK, March 11, 2020 (GLOBE NEWSWIRE) -- MeiraGTx Holdings plc (Nasdaq: MGTX), a vertically integrated, clinical stage gene therapy company, today announced financial results for the full year ended December 31, 2019 and provided an update on recent progress.

"During 2019, the MeiraGTx team reached meaningful milestones, including the initiation of two new clinical trials and our entry into a collaboration with Janssen to develop and commercialize our pipeline of inherited retinal disease treatments," said Alexandria Forbes, Ph.D., president and chief executive officer of MeiraGTx. "We have treated patients across five gene therapy clinical trials in the last year and remain committed to developing cutting-edge science that we can translate into treatments for patients affected by severe diseases. Over the next year, we expect to move inherited retinal disease programs into late-stage studies, share preliminary data from our xerostomia program and file an IND to initiate the next clinical study of AAV-GAD for Parkinson's disease."

As of December 31, 2019, MeiraGTx had cash and cash equivalents of approximately $227.4 million. The Company believes this capital will be sufficient to fund operating expenses and capital expenditure requirements into 2022.

Recent Clinical Development Highlights and Anticipated 2020 Milestones

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

- MeiraGTx continues to activate clinical trial sites in the Company's recently initiated Phase 1/2 AQUAx study, with patients now being enrolled at three of five expected study sites. Dosing in the first cohort was completed in the first quarter of 2020.
- The Company's single center Phase 1 dose-finding study of AAV-AQP1 also continues to enroll patients at the National Institutes of Health (NIH). Enrollment in the fourth dose escalation cohort is now ongoing.
- MeiraGTx expects to report preliminary data from the AQUAx clinical trial in the second half of 2020.

Janssen-partnered investigational gene therapies for the treatment of inherited retinal diseases:

- In 2019, MeiraGTx and Janssen Pharmaceuticals, Inc. (Janssen), part of the Janssen Pharmaceutical Companies of Johnson & Johnson, entered into a worldwide collaboration and license agreement to develop, manufacture and commercialize gene therapies for inherited retinal diseases, including MeiraGTx's ongoing Phase 1/2 studies of AAV-RPGR for X-linked retinitis pigmentosa (XLRP) and AAV-CNGB3 and AAV-CNGA3 for achromatopsia (ACHM).
- In the first quarter of 2020, the European Medicines Agency (EMA) granted Priority Medicines (PRIME) and Advanced Therapy Medicinal Product (ATMP) designations to AAV-RPGR. PRIME designation was granted based on clinical data from the ongoing Phase 1/2 trial. To be awarded PRIME, a medicine must demonstrate potential to benefit patients with unmet medical needs based on early clinical data. MeiraGTx expects to engage with global regulatory authorities in 2020 with the goal of optimizing and accelerating the development of AAV-RPGR.
- MeiraGTx expects to report data from the ongoing clinical trial of AAV-RPGR in 2020.
- MeiraGTx continues to advance the Company's ongoing Phase 1/2 studies of AAV-CNGB3 and AAV-CNGA3 for the treatment of achromatopsia (ACHM) associated with mutations in the *CNGB3* and *CNGA3* genes.

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

- MeiraGTx anticipates that the Company will file an Investigational New Drug application (IND) in the second half of 2020.

AAV-RPE65 for the treatment of *RPE65*-Associated Retinal Dystrophy:

- In 2019, MeiraGTx presented data from a Phase 1/2 clinical trial which demonstrated that, in addition to meeting its primary endpoint of safety, AAV-RPE65 demonstrated statistically significant improvement across several assessments of visual function. MeiraGTx expects to meet with global regulatory authorities in 2020 to determine the regulatory pathway for AAV-RPE65.

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

Recent Corporate Development Highlights and Anticipated 2020 Milestones

Second Viral Vector Manufacturing Facility and Plasmid Production Facility

- MeiraGTx has completed feasibility studies for a second cGMP viral vector manufacturing facility and a cGMP plasmid production facility.
- The Company anticipates that its plasmid production facility will be operational by the end of 2020 and expects to initiate construction of its viral vector facility in mid-2020.

Expanding Clinical, Regulatory, Manufacturing, MSAT and Preclinical Development Teams

- MeiraGTx continues to substantially increase key personnel across functional areas to support the Company's broad pipeline of optimized investigational gene therapies. The MeiraGTx team now includes more than 155 full-time employees.

Financial Results

Cash and cash equivalents were $227.4 million as of December 31, 2019, compared to $68.1 million as of December 31, 2018.

Research and development expenses were $24.9 million for the year ended December 31, 2019, compared to $33.6 million for the year ended December 31, 2018. The decrease of $8.7 million was primarily due to research funding provided to us under the Janssen collaboration agreements in the amount of $27.9 million and an increase in the research and development credit in the United Kingdom of $8.6 million. These were partially offset by increases in costs related to our ocular and xerostomia clinical trials, clinical trial material manufacturing, restructuring of certain licenses, payroll, share-based compensation and rent.

General and administrative expenses were $46.7 million for the year ended December 31, 2019, compared to $44.5 million for the year ended December 31, 2018. The increase of $2.2 million was primarily due to increases in legal fees, rent, insurance, consulting fees, travel expenses, director fees and other general and administrative expenses, which was partially offset by decreases in share-based compensation and payroll.

Foreign currency gain was $3.2 million for the year ended December 31, 2019 compared to a loss of $3.8 million for the year ended December 31, 2018. The change of $7.6 million was primarily due to a strengthening of the pound sterling against the U.S. dollar in 2019.

Net loss attributable to ordinary shareholders for the year ended December 31, 2019 was $54.8 million, or $1.65 basic and diluted net loss per ordinary share, compared to a net loss attributable to ordinary shareholders of $84.7 million, or $4.47 basic and diluted net loss per ordinary share for the year ended December 31, 2018.

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, 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; 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 Annual Report on Form 10-K for the year ended December 31, 2019, 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:
MeiraGTx
Elizabeth Broder
(646) 860-7983
Investors@meiragtx.com

or

Media:
W2O pure
Christiana Pascale
(212) 267-6722
cpascale@purecommunications.com

MEIRAGTX HOLDINGS PLC AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	For the Year Ended December 31,	
	2019	2018
License revenue - related party	$ 13,291,956	$ —
Operating expenses:		
General and administrative	$ 46,684,297	$ 44,483,938
Research and development	24,875,659	33,620,223
Total operating expenses	71,559,956	78,104,161
Loss from operations	(58,268,000)	(78,104,161)
Other non-operating income (expense):		
Foreign currency gain (loss)	3,199,774	(3,824,383)
Change in fair value of warrant liability	—	(1,514,775)
Other income	—	83,075
Interest income	370,603	53,408
Interest expense	(48,612)	(33,429)
Loss before income taxes	(54,746,235)	(83,340,265)
Benefit for income taxes	—	474,391
Net loss	(54,746,235)	(82,865,874)
Other comprehensive (loss) income:		
Foreign currency translation, net of tax of $0 and $474,391 in 2019 and 2018, respectively	(2,087,708)	2,316,143
Total comprehensive loss	$ (56,833,943)	$ (80,549,731)
Net loss	$ (54,746,235)	$ (82,865,874)
Accretion on convertible preferred C shares and warrants	—	(1,806,512)
Net loss attributable to ordinary shareholders	$ (54,746,235)	$ (84,672,386)
Basic and diluted adjusted net loss per ordinary share	$ (1.65)	$ (4.47)
Weighted-average number of ordinary shares outstanding	33,161,860	18,948,520

MEIRAGTX HOLDINGS PLC AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	December 31, 2019	December 31, 2018
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 227,233,384	$ 68,080,175
Accounts receivable - related party	23,337,377	—
Prepaid expenses	4,464,085	1,937,785
Tax incentive receivable	11,974,437	3,416,932
Other current assets	1,970,585	1,217,173
Total Current Assets	268,979,868	74,652,065
Property and equipment, net	23,858,108	22,014,237
Security deposits	951,138	105,085
In-process research and development	777,655	—
Restricted cash	123,376	123,376
Other assets	195,053	—
Right-of-use assets	29,002,448	—
TOTAL ASSETS	$ 323,887,646	$ 96,894,763
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 3,759,339	$ 3,042,861
Accrued expenses	18,083,757	11,991,697
Lease obligations, current	1,674,210	27,199
Deferred revenue - related party, current	25,678,515	—
Other current liabilities	—	437,053
Total Current Liabilities	49,195,821	15,498,810
Deferred revenue - related party	60,535,576	—
Lease obligations	21,504,340	7,097
Asset retirement obligations	1,654,755	128,119
Deferred rent	—	201,264
Deferred income tax liability	195,053	—
TOTAL LIABILITIES	133,085,545	15,835,290
COMMITMENTS		
SHAREHOLDERS' EQUITY:		
Ordinary Shares, $0.00003881 par value, 1,288,327,750 authorized 36,791,906 issued and outstanding at December 31, 2019 27,386,632 issued and outstanding at December 31, 2018	1,429	1,064
Capital in excess of par value	395,630,666	229,054,460
Accumulated other comprehensive (loss) income	(1,794,042)	293,666
Accumulated deficit	(203,035,952)	(148,289,717)
Total Shareholders' Equity	190,802,101	81,059,473
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 323,887,646	$ 96,894,763