

**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): November 7, 2019

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

Cayman Islands
(State or other jurisdiction of
incorporation or organization)

001-38520
(Commission
File Number)

Not applicable
(I.R.S. Employer
Identification No.)

450 East 29th Street, 15th 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 November 7, 2019 MeiraGTx Holdings plc (the “Company”) issued a press release announcing its financial results for the quarter ended September 30, 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.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release of MeiraGTx Holdings plc, dated November 7, 2019.

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: November 7, 2019

MEIRAGTX HOLDINGS PLC

By: /s/ Richard Giroux

Name: Richard Giroux

Title: Chief Financial Officer and Chief
Operating Officer



MeiraGTx Reports Third Quarter 2019 Financial Results

LONDON and NEW YORK, November 7, 2019 (GLOBE NEWSWIRE) — MeiraGTx Holdings plc (Nasdaq: MGTX), a vertically integrated, clinical stage gene therapy company, today announced financial results for the quarter ended September 30, 2019 and provided an update on recent progress.

“Over the course of the third quarter, we continued to advance our broad pipeline of investigational gene therapies,” said Alexandria Forbes, Ph.D., president and CEO, MeiraGTx. “In recent months, we have shared data from our first completed clinical trial with the medical community at the annual meetings of the Retina Society and the American Academy of Ophthalmology. Additionally, we continue to make strategic investments to develop next-generation, best-in-class gene therapy technologies, including our recent initiative to build a second cGMP manufacturing facility and to bring plasmid production in house.”

Third Quarter 2019 Clinical Development Highlights

Phase 1/2 trial of AAV-RPE65 for RPE65-Associated Retinal Dystrophy: Data from the trial were presented in September 2019 at the 52nd Annual Scientific Meeting of the Retina Society and in October 2019 at the American Academy of Ophthalmology Annual Meeting. These data demonstrated that AAV-RPE65 improved functional vision, as assessed by vision-guided mobility maze, retinal function, as assessed by static perimetry, and several measures of central vision, including central retinal sensitivity, visual acuity and contrast sensitivity.

Phase 1/2 AQUAx trial of AAV-AQP1 for Grade 2/3 Radiation-Induced Xerostomia: MeiraGTx initiated the open-label, multi-center, dose-finding Phase 1/2 trial in the third quarter of 2019 and is enrolling patients with radiation-induced Grade 2/3 xerostomia following treatment for head and neck cancer.

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 third dose escalation cohort was completed in the third quarter of 2019.

Janssen-partnered investigational gene therapies: MeiraGTx and Janssen Pharmaceuticals, Inc. (Janssen), part of the Janssen Pharmaceutical Companies of Johnson & Johnson, continue to advance a portfolio of partnered gene therapies for the treatment of inherited retinal diseases, including the Company’s ongoing Phase 1/2 studies of AAV-RPGR for X-linked retinitis pigmentosa (XLRP) and AAV-CNGB3 and AAV-CNGA3 for achromatopsia (ACHM).



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

Third Quarter 2019 Corporate Highlights

Expanding manufacturing capabilities: In August 2019, MeiraGTX raised approximately \$75 million of gross proceeds in a public offering of approximately 3.2 million of its ordinary shares. The Company intends to use a portion of the proceeds of this offering to expand its manufacturing capabilities, including building a second cGMP viral vector manufacturing facility as well as a cGMP plasmid production facility. MeiraGTX is completing feasibility studies for the second facility and expects to begin construction in 2020.

Third Quarter 2019 Financial Results

As of September 30, 2019, MeiraGTX had cash and cash equivalents of approximately \$253.3 million. This capital will be sufficient to fund its operating expenses and capital expenditure requirements into 2022.

Comparison of Three Months Ended September 30, 2019 and 2018

General and administrative expenses were \$9.9 million for the three months ended September 30, 2019, compared to \$6.6 million for the three months ended September 30, 2018. The increase of \$3.3 million was primarily due to increases in payroll, insurance and rent expenses, consulting fees and share-based compensation.

Research and development expenses for the three months ended September 30, 2019 were \$4.6 million, compared to \$8.1 million for the three months ended September 30, 2018. The decrease of \$3.5 million was primarily due to an increase in research funding provided by our license and collaboration agreements with Janssen, which was partially offset by increases in costs related to our clinical trials and to the manufacture of material for our clinical trials.

Foreign currency gain was \$0.1 million for the three months ended September 30, 2019 compared to a loss of \$0.7 million for the three months ended September 30, 2018. The increase of \$0.8 million was primarily due to a strengthening of the U.S. dollar against the pound sterling during the three months ended September 30, 2019.

Net loss for the three months ended September 30, 2019 was \$10.5 million, or \$(0.30) basic and diluted net loss per ordinary share, compared to a net loss of \$15.4 million, or \$(0.59) basic and diluted net loss per ordinary share for the three months ended September 30, 2018.

MeiraGTX ended the third quarter of 2019 with \$253.3 million in cash and cash equivalents, compared to \$88.5 million as of September 30, 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 and xerophthalmia. 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 2019 milestones regarding our pre-clinical and clinical data and reporting of such data and the timing of results of data in connection with AAV-AQP1 for the treatment of patients with radiation-induced Grade 2/3 xerostomia, 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; 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 Quarterly



Report on Form 10-Q for the quarterly period ended September 30, 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.

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**MEIRAGTX HOLDINGS PLC AND SUBSIDIARIES CONDENSED
CONSOLIDATED BALANCE SHEETS**

	September 30, 2019 (unaudited)	December 31, 2018
<u>ASSETS</u>		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 253,330,623	\$ 68,080,175
Prepaid expenses	6,248,981	1,937,785
Other current assets	11,509,144	4,634,105
Total Current Assets	<u>271,088,748</u>	<u>74,652,065</u>
Right-of-use assets	28,801,757	—
Property and equipment, net	16,899,147	22,014,237
Security deposits	839,149	105,085
Restricted cash	123,376	123,376
TOTAL ASSETS	<u>\$ 317,752,177</u>	<u>\$ 96,894,763</u>
<u>LIABILITIES AND SHAREHOLDERS' EQUITY</u>		
CURRENT LIABILITIES:		
Accounts payable	\$ 3,798,441	\$ 3,042,861
Accrued expenses	9,346,895	11,991,697
Lease obligations, current	2,028,689	27,199
Deferred revenue - related party, current	24,115,777	—
Other current liabilities	—	437,053
Total Current Liabilities	<u>39,289,802</u>	<u>15,498,810</u>
Deferred revenue - related party	62,837,715	—
Lease obligations	20,600,077	7,097
Deferred rent	—	201,264
Asset retirement obligations	131,213	128,119
TOTAL LIABILITIES	<u>122,858,807</u>	<u>15,835,290</u>
COMMITMENTS		
SHAREHOLDERS' EQUITY:		
Ordinary Shares, \$0.00003881 par value, 1,288,327,750 authorized 36,571,722 issued and outstanding at September 30, 2019 27,386,632 issued and outstanding at December 31, 2018	1,420	1,064
Capital in excess of par value	390,053,479	229,054,460
Accumulated other comprehensive income	2,393,372	293,666
Accumulated deficit	(197,554,901)	(148,289,717)
Total Shareholders' Equity	<u>194,893,370</u>	<u>81,059,473</u>
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	<u>\$ 317,752,177</u>	<u>\$ 96,894,763</u>

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

	For the Three-Month Period Ended September 30,		For the Nine-Month Period Ended September 30,	
	2019	2018	2019	2018
License revenue - related party	\$ 3,582,586	\$ —	\$ 6,349,222	\$ —
Operating expenses:				
General and administrative	\$ 9,874,810	\$ 6,629,052	\$ 31,811,456	\$ 35,129,120
Research and development	4,614,446	8,109,160	27,362,432	22,827,176
Total operating expenses	<u>14,489,256</u>	<u>14,738,212</u>	<u>59,173,888</u>	<u>57,956,296</u>
Loss from operations	(10,906,670)	(14,738,212)	(52,824,666)	(57,956,296)
Other non-operating income (expense):				
Foreign currency gain (loss)	115,470	(677,488)	3,117,047	(2,425,488)
Change in fair value of warrant liability	—	—	—	(1,514,775)
Other income	—	—	—	83,075
Interest income	959	264	40,686	50,926
Interest expense	(9,283)	(9,508)	(28,311)	(46,571)
Loss before income taxes	(10,799,524)	(15,424,944)	(49,695,244)	(61,809,129)
Benefit for income taxes	338,670	—	430,060	—
Net loss	<u>(10,460,854)</u>	<u>(15,424,944)</u>	<u>(49,265,184)</u>	<u>(61,809,129)</u>
Other comprehensive income:				
Foreign currency translation, net of tax of \$338,670 and \$0 for the three-month periods ended September 30, 2019 and 2018, respectively and \$430,060 and \$0 for the nine-month periods ended September 30, 2019 and 2018, respectively	1,653,507	508,758	2,099,706	1,730,000
Total comprehensive loss	<u>\$ (8,807,347)</u>	<u>\$ (14,916,186)</u>	<u>\$ (47,165,478)</u>	<u>\$ (60,079,129)</u>
Net loss	<u>\$ (10,460,854)</u>	<u>\$ (15,424,944)</u>	<u>\$ (49,265,184)</u>	<u>\$ (61,809,129)</u>
Accretion on convertible preferred C shares and warrants	—	—	—	(1,806,512)
Adjusted net loss	<u>\$ (10,460,854)</u>	<u>\$ (15,424,944)</u>	<u>\$ (49,265,184)</u>	<u>\$ (63,615,641)</u>
Basic and diluted adjusted net loss per ordinary share	<u>\$ (0.30)</u>	<u>\$ (0.59)</u>	<u>\$ (1.53)</u>	<u>\$ (3.89)</u>
Weighted-average number of ordinary shares outstanding	<u>34,663,623</u>	<u>26,340,450</u>	<u>32,111,733</u>	<u>16,355,849</u>