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 5, 2020**

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 2.02. Results of Operations and Financial Condition.

On November 5, 2020, MeiraGTx Holdings plc (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 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 November 5, 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: November 5, 2020

MEIRAGTX HOLDINGS PLC

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

MeiraGTx Reports Third Quarter 2020 Financial Results

- *MeiraGTx preparing to initiate Phase 3 trial of AAV-RPGR*
- *Plasmid production facility expected to be completed year-end 2020*

LONDON and NEW YORK, November 5, 2020 -- MeiraGTx Holdings plc (Nasdaq: MGTX), a vertically integrated, clinical stage gene therapy company, today announced financial results for the third quarter ended September 30, 2020 and provided an update on recent clinical development and business progress.

"As we prepare to initiate our first pivotal trial, we continue to be encouraged by data emerging from our Phase 1/2 clinical trial of AAV-RPGR for the treatment of X-linked retinitis pigmentosa," said Alexandria Forbes, Ph.D., president and chief executive officer of MeiraGTx. "We continued to make significant progress this quarter advancing our programs, and we look forward to providing additional clinical updates through the end of the year."

MeiraGTx and Janssen Pharmaceuticals, Inc. (Janssen), one of the Janssen Pharmaceutical Companies of Johnson & Johnson, are jointly developing AAV-RPGR as part of a broader collaboration to develop and commercialize gene therapies for the treatment of inherited retinal diseases.

As of September 30, 2020, MeiraGTx had cash, cash equivalents and restricted cash of $179.3 million. In addition, the Company expects approximately $26.6 million in receivables from development partner Janssen in the next 90 days. MeiraGTx believes this capital will be sufficient to fund operating expenses and capital expenditure requirements into 2022.

Recent Clinical Development and Corporate Updates

AAV-RPGR for the Treatment of X-Linked Retinitis Pigmentosa (XLRP)

- Nine-month data from MeiraGTx's ongoing Phase 1/2 clinical study (MGT009) of AAV-RPGR were presented at the EURETINA 2020 Virtual Meeting in October. Data at the nine-month time point continued to demonstrate significant, sustained vision improvement following treatment with AAV-RPGR in both the low (n=3) and intermediate (n=4) dose cohorts.
- Twelve-month data from the study will be presented at the American Academy of Ophthalmology (AAO) 2020 Virtual Annual Meeting on November 13, 2020.
- MeiraGTx and development partner Janssen are preparing to initiate the pivotal Phase 3 Lumeos clinical trial of AAV-RPGR in patients with XLRP.

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

- In response to the COVID-19 pandemic, MeiraGTx is working with clinical sites to enable continuity of the AQUAx clinical trial in accordance with local regulations and site policies. Monitoring of enrolled subjects continues and start up activities for new sites have resumed.
- MeiraGTx expects to report preliminary data from the first treatment cohort of the AQUAx trial by the end of 2020.

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

- MeiraGTx continues to expect to file an Investigational New Drug (IND) application in the first half of 2021 following the release of the clinical material manufactured at the Company's London cGMP facility.

Manufacturing and Supply Chain

- Construction of MeiraGTx's Shannon, Ireland manufacturing campus is progressing. The campus will house the Company's first cGMP plasmid production facility and MeiraGTx's second cGMP viral vector manufacturing facility. The Shannon campus will provide additional flexibility and large-scale capacity for clinical and commercial supply of MeiraGTx's gene therapy product candidates.
- Construction and commissioning activity remain on track, with the plasmid facility expected to be completed at the end of 2020, and the viral vector facility expected to be completed by year-end 2021. Hiring of highly skilled bio-process engineering, manufacturing and quality professionals in Ireland has commenced with several new employees expected by the end of 2020.
- MeiraGTx's cGMP viral vector manufacturing facility in London was re-certified in the second quarter of 2020 by the Medicines & Healthcare Products Regulatory Agency (MHRA).

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

Financial Results

License revenue was $5.1 million for the quarter ended September 30, 2020, compared to $3.6 million for the quarter ended September 30, 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.

Research and development expenses were $4.6 million for the quarter ended September 30, 2020, compared to $4.6 million for the quarter ended September 30, 2019. Expenses primarily consisted of costs related to pre-clinical research and clinical trials, costs related to the manufacture of material for clinical trials, payroll and payroll related costs and share-based compensation, which were partially offset by research funding provided under our collaboration agreement with Janssen.

General and administrative expenses were $8.9 million for the quarter ended September 30, 2020, compared to $9.9 million for the quarter ended September 30, 2019. The decrease was primarily due to decreases in payroll and payroll related costs and travel costs, which were partially offset by increases in rent and facilities costs, insurance costs, legal and accounting fees and other office-related costs.

Foreign currency gain was $1.9 million for the quarter ended September 30, 2020, compared to a gain of $0.1 million for the quarter ended September 30, 2019. The increase was primarily due to a weakening of the U.S. dollar against the pound sterling.

Net loss attributable to ordinary shareholders for the quarter ended September 30, 2020 was $6.4 million, or $ (0.17) basic and diluted net loss per ordinary share, compared to a net loss attributable to ordinary shareholders of $10.5 million, or $(0.30) basic and diluted net loss per ordinary share for the quarter ended September 30, 2019.

Cash, cash equivalents and restricted cash were $179.3 million for the quarter ended September 30, 2020, compared to $253.3 million as of September 30, 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 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, raise 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 September 30, 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 STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(unaudited)

	For the Three-Month Period Ended September 30,		For the Nine-Month Period Ended September 30,	
	2020	2019	2020	2019
License revenue - related party	$ 5,091,832	$ 3,582,586	$ 11,775,113	$ 6,349,222
Operating expenses:				
General and administrative	8,896,111	9,874,810	32,199,515	31,811,456
Research and development	4,626,085	4,614,446	28,911,490	27,362,432
Total operating expenses	13,522,196	14,489,256	61,111,005	59,173,888
Loss from operations	(8,430,364)	(10,906,670)	(49,335,892)	(52,824,666)
Other non-operating income (expense):				
Foreign currency gain	1,875,427	115,470	766,860	3,117,047
Interest income	158,346	959	1,141,321	40,686
Interest expense	(35,136)	(9,283)	(103,147)	(28,311)
Loss before income taxes	(6,431,727)	(10,799,524)	(47,530,858)	(49,695,244)
Benefit for income taxes	—	338,670	—	430,060
Net loss	(6,431,727)	(10,460,854)	(47,530,858)	(49,265,184)
Other comprehensive (loss) income:				
Foreign currency translation (loss) gain	(4,121,227)	1,653,507	342,289	2,099,706
Total comprehensive loss	$ (10,552,954)	$ (8,807,347)	$ (47,188,569)	$ (47,165,478)
Net loss	$ (6,431,727)	$ (10,460,854)	$ (47,530,858)	$ (49,265,184)
Basic and diluted adjusted net loss per ordinary share	$ (0.17)	$ (0.30)	$ (1.29)	$ (1.53)
Weighted-average number of ordinary shares outstanding	37,223,375	34,663,623	36,940,372	32,111,733

See Notes to Condensed Consolidated Financial Statements

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

	September 30, 2020	December 31, 2019
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 179,084,386	$ 227,233,384
Restricted cash	250,526	—
Accounts receivable - related party	26,639,805	23,337,377
Prepaid expenses	4,001,502	4,464,085
Tax incentive receivable	7,087,253	11,974,437
Other current assets	818,671	1,970,585
Total Current Assets	217,882,143	268,979,868
Property and equipment, net	34,820,814	23,858,108
Security deposits	737,720	951,138
In-process research and development	810,357	777,655
Restricted cash	—	123,376
Other assets	203,255	195,053
Right-of-use assets	38,591,434	29,002,448
TOTAL ASSETS	$ 293,045,723	$ 323,887,646
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 5,195,937	$ 3,759,339
Accrued expenses	15,563,482	18,083,757
Lease obligations, current	2,116,018	1,674,210
Deferred revenue - related party, current	23,715,116	25,678,515
Other current liabilities	17,639	—
Total Current Liabilities	46,608,192	49,195,821
Deferred revenue - related party	48,279,463	60,535,576
Lease obligations	17,127,159	21,504,340
Asset retirement obligations	1,741,407	1,654,755
Deferred income tax liability	203,255	195,053
TOTAL LIABILITIES	113,959,476	133,085,545
COMMITMENTS		
SHAREHOLDERS' EQUITY:		
Ordinary Shares, $0.00003881 par value, 1,288,327,750 authorized, 38,412,163 and 36,791,906 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	1,491	1,429
Capital in excess of par value	431,103,319	395,630,666
Accumulated other comprehensive loss	(1,451,753)	(1,794,042)
Accumulated deficit	(250,566,810)	(203,035,952)
Total Shareholders' Equity	179,086,247	190,802,101
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 293,045,723	$ 323,887,646

See Notes to Condensed Consolidated Financial Statements