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 6, 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 August 6, 2020 MeiraGTx Holdings plc (the "Company") issued a press release announcing its financial results for the quarter ended June 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 August 6, 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: August 6, 2020

MEIRAGTX HOLDINGS PLC

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

Exhibit 99.1

MeiraGTx Reports Second Quarter 2020 Financial Results

- *Positive initial data from Phase 1/2 clinical trial of AAV-RPGR for the treatment of XLRP recently presented*
- *AAV-RPGR to advance into Phase 3 Lumeos clinical trial*
- *Expands manufacturing capabilities with new facilities in Ireland*

LONDON and NEW YORK, August 6, 2020 (GLOBE NEWSWIRE) -- MeiraGTx Holdings plc (Nasdaq: MGTX), a vertically integrated, clinical stage gene therapy company, today announced financial results for the second quarter ended June 30, 2020 and provided an update on recent clinical development and business progress, including the Company's new cGMP viral vector manufacturing and plasmid production facilities in Shannon, Ireland.

"The first half of 2020 has been marked by notable achievements for MeiraGTx, including the recent presentation of positive clinical data on our investigational therapy for people with the severe inherited retinal disease X-linked retinitis pigmentosa, which demonstrate that AAV-RPGR treatment improved vision and support advancing the program into a pivotal trial," said Alexandria Forbes, Ph.D., president and chief executive officer of MeiraGTx.

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 we advance and expand our clinical pipeline of potential gene therapy products, our flexible and scalable cGMP manufacturing capabilities become increasingly critical in enabling the efficient and timely development of these potential therapies," continued Dr. Forbes. "We look forward to working with the local community in Shannon, Ireland as we establish our second cGMP viral vector manufacturing facility and our cGMP plasmid production facility. We expect our plasmid production facility to be operational by the end of 2020, and our second viral vector manufacturing facility to be operational by the end of 2021."

As of June 30, 2020, MeiraGTx had cash and cash equivalents of $194.8 million. In addition, the Company expects approximately $24.4 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

- Initial positive clinical data from MeiraGTx's ongoing Phase 1/2 clinical study (MGT009) of AAV-RPGR were presented as a late-breaker oral presentation at the American Society of Retina Specialists (ASRS) 2020 Virtual Annual Meeting in July 2020.
- Six-month data from the dose escalation portion of the trial (n=10) demonstrated meaningful improvement from baseline in retinal sensitivity in the low (n=3) and intermediate (n=4)

dose cohorts. Importantly, these improvements were evident when assessed with two perimetry approaches (static perimetry and microperimetry) and three analysis metrics (mean retinal sensitivity, central 30° hill-of-vision volumetric measure (V30), and pointwise comparison).
- Based on the encouraging safety and efficacy data demonstrated in the MGT009 trial to date, MeiraGTx and Janssen expect to advance AAV-RPGR into the Phase 3 Lumeos clinical trial for the treatment of patients with XLRP caused by mutations in *RPGR* gene.

AAV-AQP1 for the Treatment of Grade 2/3 Radiation-Induced Xerostomia
- In response to the COVID-19 pandemic, MeiraGTx continues to work closely with clinical sites to enable continuity of the Company's ongoing AQUAx clinical trial. New patient enrollment in the trial has resumed, and patients who have been treated in the trial are continuing to undergo post-treatment follow-up assessments.
- MeiraGTx anticipates reporting preliminary clinical data from the AAV-AQP1 program by the end of 2020.

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

- Manufacturing of AAV-GAD material is ongoing at the Company's London cGMP facility. MeiraGTx expects to file an Investigational New Drug (IND) application in early 2021 following the release of the clinical material.

Manufacturing and Supply Chain

- MeiraGTx has selected Shannon, Ireland as the site of the Company's second cGMP viral vector manufacturing facility and cGMP plasmid production facility. These facilities will be designed for the manufacture of commercial-grade gene therapies in a fully integrated manner supported by MeiraGTx's global quality assurance organization. MeiraGTx expects the Irish facilities to provide additional flexibility as well as further large-scale capacity for clinical and commercial supply of its gene therapy product candidates from first-in-man clinical trials through potential commercialization. This project is supported by the Irish Government through IDA Ireland.
- The plasmid production facility is expected to be operational by the end of 2020, and the viral vector manufacturing facility is expected to be operational by the end of 2021.

Strengthened Senior Leadership Team
- MeiraGTx appointed Robert K. Zeldin, M.D. as Chief Medical Officer. In this role, Dr. Zeldin oversees the development of MeiraGTx's six clinical stage gene therapy programs.

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

Financial Results

License revenue was $2.5 million for the quarter ended June 30, 2020, compared to $2.0 million for the quarter ended June 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 $16.2 million for the quarter ended June 30, 2020, compared to $9.8 million for the quarter ended June 30, 2019. The increase of $6.4 million was

primarily due to an increase for the non-cash acquisition costs of Emrys Bio, Inc. and increases in costs related to the manufacture of material for clinical trials, payroll and payroll related costs and share-based compensation, which was partially offset by an increase in research funding provided under our collaboration agreement with Janssen and a decrease in costs related to our clinical trials.

General and administrative expenses were $11.5 million for the quarter ended June 30, 2020, compared to $13.4 million for the quarter ended June 30, 2019. The decrease of $1.9 million was primarily due to decreases in payroll and payroll related costs, which was partially offset by increases in rent and facilities costs, insurance costs and consulting fees.

Foreign currency loss was $0.4 million for the quarter ended June 30, 2020, compared to a gain of $0.3 million for the quarter ended June 30, 2019. The increase in the loss of $0.7 million was primarily due to a strengthening of the U.S. dollar against the pound sterling during the three months ended June 30, 2020.

Net loss attributable to ordinary shareholders for the quarter ended June 30, 2020 was $25.4 million, or $0.69 basic and diluted net loss per ordinary share, compared to a net loss attributable to ordinary shareholders of $20.8 million, or $0.63 basic and diluted net loss per ordinary share for the quarter ended June 30, 2019.

Cash and cash equivalents were $194.8 million for the quarter ended June 30, 2020, compared to $204.4 million as of June 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 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 June 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 BALANCE SHEETS
(unaudited)

	June 30, 2020	December 31, 2019
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 194,811,181	$ 227,233,384
Accounts receivable - related party	24,432,392	23,337,377
Prepaid expenses	7,318,772	4,464,085
Tax incentive receivable	6,777,863	11,974,437
Other current assets	1,868,559	1,970,585
Total Current Assets	235,208,767	268,979,868
Property and equipment, net	27,807,875	23,858,108
Security deposits	705,515	951,138
In-process research and development	774,727	777,655
Restricted cash	—	123,376
Other assets	194,318	195,053
Right-of-use assets	25,920,174	29,002,448
TOTAL ASSETS	$ 290,611,376	$ 323,887,646
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 3,089,350	$ 3,759,339
Accrued expenses	18,491,860	18,083,757
Lease obligations, current	2,137,788	1,674,210
Deferred revenue - related party, current	23,003,106	25,678,515
Total Current Liabilities	46,722,104	49,195,821
Deferred revenue - related party	50,691,547	60,535,576
Lease obligations	18,555,378	21,504,340
Asset retirement obligations	1,682,515	1,654,755
Deferred income tax liability	194,318	195,053
TOTAL LIABILITIES	117,845,862	133,085,545
COMMITMENTS		
SHAREHOLDERS' EQUITY:		
Ordinary Shares, $0.00003881 par value, 1,288,327,750 authorized, 37,362,416 and 36,791,906 shares issued and outstanding at June 30, 2020 and December 31, 2019, respectively	1,451	1,429
Capital in excess of par value	414,229,672	395,630,666
Accumulated other comprehensive income (loss)	2,669,474	(1,794,042)
Accumulated deficit	(244,135,083)	(203,035,952)
Total Shareholders' Equity	172,765,514	190,802,101
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 290,611,376	$ 323,887,646

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

	For the Three-Month Periods Ended June 30,		For the Six-Month Periods Ended June 30,	
	2020	2019	2020	2019
License revenue - related party	$ 2,473,705	$ 1,981,676	$ 6,683,281	$ 2,766,636
Operating expenses:				
General and administrative	11,497,270	13,437,171	23,303,404	21,936,646
Research and development	16,202,065	9,771,754	24,285,405	22,747,983
Total operating expenses	27,699,335	23,208,925	47,588,809	44,684,629
Loss from operations	(25,225,630)	(21,227,249)	(40,905,528)	(41,917,993)
Other non-operating income (expense):				
Foreign currency (loss) gain	(351,863)	283,175	(1,108,567)	3,001,575
Interest income	193,604	39,726	982,975	39,726
Interest expense	(34,045)	(9,454)	(68,011)	(19,028)
Loss before income taxes	(25,417,934)	(20,913,802)	(41,099,131)	(38,895,720)
Benefit for income taxes	—	91,390	—	91,390
Net loss	(25,417,934)	(20,822,412)	(41,099,131)	(38,804,330)
Other comprehensive income:				
Foreign currency translation gain, net of tax of $0, for the three-month and six-month periods ended June 30, 2020, and $91,390 for the three-month and six-month periods ended June 30, 2019	517,592	1,579,882	4,463,516	446,199
Total comprehensive loss	$ (24,900,342)	$ (19,242,530)	$ (36,635,615)	$ (38,358,131)
Net loss	$ (25,417,934)	$ (20,822,412)	$ (41,099,131)	$ (38,804,330)
Basic and diluted net loss per ordinary share	$ (0.69)	$ (0.63)	$ (1.12)	$ (1.26)
Weighted-average number of ordinary shares outstanding	36,969,682	32,827,029	36,797,316	30,814,639