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 11, 2021**

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 May 11, 2021, MeiraGTx Holdings plc (the "Company") issued a press release announcing its financial results for the quarter ended March 31, 2021. 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 11, 2021.
104	Cover Page Interactive Data File (the cover page XBRL tags are embedded in the Inline XBRL document).

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 11, 2021

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 2021 Financial and Operational Results

LONDON and NEW YORK, May 11, 2021 (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, 2021 and provided an update on recent progress.

“During the first quarter of 2021, we continued to advance our clinical and preclinical programs, as well as our proprietary cGMP manufacturing process. We are progressing rapidly with our riboswitch gene regulation technology platform and we are excited to share *in-vivo* data later this year” said Alexandria Forbes, Ph.D., president and chief executive officer of MeiraGTx. “This will be an important year for MeiraGTx as the Company prepares for the initiation of two Phase 3 pivotal trials in X-linked retinitis pigmentosa and *RPE65*-associated retinal dystrophy, both with material made from our internal cGMP manufacturing facility in London. With COVID-19 restrictions easing, we are on track to complete enrollment in our Phase 1 AQUAx study in grade 2/3 radiation-induced xerostomia this year as well as open our next study of AAV-GAD for Parkinson’s Disease. We are also progressing several of our pre-clinical programs towards INDs in 2022.”

As of March 31, 2021, MeiraGTx had cash and cash equivalents of approximately $199.4 million, as well as approximately $12.0 million due in receivables from development partner Janssen Pharmaceuticals, Inc. (Janssen), one of the Janssen Pharmaceutical Companies of Johnson & Johnson, as part of a broader collaboration to develop and commercialize gene therapies for the treatment of inherited retinal diseases.

The Company believes it will have sufficient capital to fund operating expenses and capital expenditure requirements into mid-2023.

Recent Corporate and Clinical Development Highlights

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

- MeiraGTx and Janssen continue to prepare for initiation of the Phase 3 Lumeos clinical trial.
- MeiraGTx and Janssen intend to present additional data from the Phase 1/2 clinical trial of X-linked retinitis pigmentosa (MGT009) at medical meetings later this year.

AAV-RPE65 for the Treatment of *RPE65*-associated Retinal Dystrophy:

- MeiraGTx continues to anticipate initiating a Phase 3 pivotal trial of AAV-RPE65 in the second half of 2021.

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

- Dosing in the second cohort of the AQUAx phase 1 trial is ongoing and the Company expects to complete enrollment in 2021. Four clinical sites are now open in the U.S.
- The Company is currently planning a phase 2 study and expects to initiate this trial in the second half of 2022.

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

- The Company expects to file an Investigational New Drug (IND) application in the third quarter of 2021 with material manufactured from its cGMP facility in London.

Riboswitch Gene Regulation Platform:

- MeiraGTx continues to generate *in-vivo* data demonstrating regulation of multiple therapeutic genes in multiple tissues. The Company plans to host an R&D day in the second half of 2021 detailing its proprietary riboswitch gene regulation platform, including data to support potential therapeutic targets.

AAV-CNGB3 and AAV-CNGA3 for the Treatment of Achromatopsia (ACHM):

- MeiraGTx and Janssen continue to advance the ongoing clinical development of AAV-CNGB3 and AAV-CNGA3 for the treatment of ACHM associated with mutations in the *CNGB3* and *CNGA3* genes.
  - On January 26, 2021 the U.S. Food and Drug Administration (FDA) granted Fast Track designation to the Company's AAV-CNGA3 gene therapy product candidate for the treatment of ACHM caused by mutations in the *CNGA3* gene.
  - MeiraGTx and Janssen have now completed dosing of both adults and pediatric patients in the Phase 1/2 dose escalation study of AAV-CNGA3 and expect to provide an update on further clinical studies for both AAV-CNGB3 and AAV-CNGA3 later in 2021.

Manufacturing and Supply Chain:

- MeiraGTx has made significant progress optimizing its proprietary AAV manufacturing platform process. With its internal plasmid facility now operational, the Company continues to expedite bringing the entire manufacturing process and supply chain in-house to more rapidly and cost-effectively bring innovative and potentially curative treatments to patients.

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

Financial Results

Cash, cash equivalents were $199.4 million as of March 31, 2021, compared to $209.5 million as of December 31, 2020.

License revenue was $4.6 million for the three months ended March 31, 2021, compared to $4.2 million for the three months ended March 31, 2020. This increase represents increased amortization of the $100.0 million upfront payment received in connection with the collaboration agreement with Janssen.

General and administrative expenses were $9.9 million for the three months ended March 31, 2021, compared to $11.8 million for the three months ended March 31, 2020. The decrease of $1.9 million was primarily due to a decrease of $2.4 million in payroll and payroll related costs and $1.7 million in share-based compensation due to certain restricted ordinary shares issued to certain members of senior management in June 2018 becoming fully vested in June 2020. These decreases were partially offset by increases of $0.6 million in insurance costs, $0.6 million in rent and facilities costs, $0.5 million in consulting fees, $0.2 million in legal and accounting fees, $0.1 million in depreciation and $0.2 million in other office related costs.

Research and development expenses for the three months ended March 31, 2021 were $16.7 million, compared to $8.1 million for the three months ended March 31, 2020. The increase of $8.6 million was primarily due to increases of $3.0 million in costs related to our pre-clinical research and clinical trials and $2.5 million in payroll and payroll related costs due to the expansion of our clinical trials and manufacturing capabilities. Additional increases include $1.7 million in license fees, $0.9 million in share-based compensation, $0.8 million in depreciation and a decrease of $2.3 million in research funding provided under our collaboration agreement with Janssen, which was partially offset by decreases of $2.2 million of costs related to the manufacture of material for our clinical trials and $0.4 million in other research and development costs.

Foreign currency loss was $1.6 million for the three months ended March 31, 2021 compared to a loss of $0.8 million for the three months ended March 31, 2020. The increase in the loss of $0.9 million was primarily due to a weakening of the U.S. dollar against the pound sterling and euro during the three months ended March 31, 2021.

Net loss attributable to ordinary shareholders for the quarter ended March 31, 2021 was $23.6 million, or $0.54 basic and diluted net loss per ordinary share, compared to a net loss attributable to ordinary shareholders of $15.7 million, or $0.43 basic and diluted net loss per ordinary share for the quarter ended March 31, 2020.

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: ocular, including inherited retinal diseases and large degenerative 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 2021 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," "will," "intend," "plan," "believe," "project," "forecast," "estimate," "may," "could," "should," "would," "continue," "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 March 31, 2021, 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)
(in thousands, except share and per share amounts)

	For the Three-Month Periods Ended March 31,	
	2021	2020
License revenue - related party	$ 4,595	$ 4,210
Operating expenses:		
General and administrative	9,918	11,806
Research and development	16,709	8,083
Total operating expenses	26,627	19,889
Loss from operations	(22,032)	(15,679)
Other non-operating income (expense):		
Foreign currency loss	(1,615)	(757)
Interest income	89	789
Interest expense	(59)	(34)
Net loss	(23,617)	(15,681)
Other comprehensive (loss) income:		
Foreign currency translation (loss) gain	(271)	3,946
Total comprehensive loss	$ (23,888)	$ (11,735)
Net loss	$ (23,617)	$ (15,681)
Basic and diluted net loss per ordinary share	$ (0.54)	$ (0.43)
Weighted-average number of ordinary shares outstanding	43,974,395	36,624,950

MEIRAGTX HOLDINGS PLC AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited)
(in thousands, except share and per share amounts)

	March 31, 2021	December 31, 2020
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 199,410	$ 209,520
Accounts receivable - related party	12,015	38,479
Prepaid expenses	6,365	7,082
Tax incentive receivable	7,388	12,930
Other current assets	4,948	4,565
Total Current Assets	230,126	272,576
Property and equipment, net	47,303	44,042
Intangible assets, net	2,060	2,119
In-process research and development	812	852
Security deposits	1,034	812
Other assets	204	214
Equity method and other investments	6,665	—
Right-of-use assets	51,472	43,082
TOTAL ASSETS	$ 339,676	$ 363,697
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 7,902	$ 7,134
Accrued expenses	17,248	20,861
Lease obligations, current	2,773	2,583
Deferred revenue - related party, current	25,597	23,545
Other current liabilities	—	24
Total Current Liabilities	53,520	54,147
Deferred revenue - related party	43,303	49,297
Lease obligations	19,999	19,666
Asset retirement obligations	1,856	1,814
Deferred income tax liability	204	214
TOTAL LIABILITIES	118,882	125,138
COMMITMENTS (Note 10)		
SHAREHOLDERS' EQUITY:		
Ordinary Shares, $0.00003881 par value, 1,288,327,750 authorized, 44,282,073 and 44,189,150 shares issued and outstanding at March 31, 2021 and December 31, 2020, respectively	2	2
Capital in excess of par value	510,605	504,482
Accumulated other comprehensive loss	(5,168)	(4,897)
Accumulated deficit	(284,645)	(261,028)
Total Shareholders' Equity	220,794	238,559
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 339,676	$ 363,697