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 12, 2022**

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 12, 2022, MeiraGTx Holdings plc (the "Company") issued a press release announcing its financial results for the quarter ended March 31, 2022. 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 12, 2022.
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 12, 2022

MEIRAGTX HOLDINGS PLC

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

MeiraGTx Reports First Quarter 2022 Financial and Operational Results

- *Phase 3 Lumeos Clinical Trial of Botaretigene Sparoparvovec (AAV-RPGR) for the Treatment of X-linked Retinitis Pigmentosa (XLRP) Actively Dosing Patients*

- *Phase 1 AQUAx Study of AAV-hAQP1 for Radiation-Induced Xerostomia Completed Dosing of Both Unilateral and Bilateral Cohorts in the First Quarter of 2022*

LONDON and NEW YORK, May 12, 2022 (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, 2022 and provided an update on recent progress.

“During the first quarter of this year, we continued to progress our lead program for the treatment of XLRP, botaretigene sparoparvovec, through pivotal development along with our partner Janssen,” said Alexandria Forbes, Ph.D., president and chief executive officer of MeiraGTx. “With the full operational and financial support of our partners at Janssen, this important program is proceeding as planned toward BLA submission in 2024.”

Dr. Forbes continued, “As the biotech sector endures one of the most difficult periods in its history, we continue to recognize the strategic value of the end-to-end capabilities we have built at MeiraGTx over the past seven years. Our in-house manufacturing capabilities, from plasmid supply for GMP through GMP viral vector production and analytics for GMP stability and release, allow us to advance our wholly-owned and Janssen-partnered clinical and preclinical programs in a capital-efficient way without relying on third-party suppliers. For our lead program in XLRP, we are preparing for commercial supply including all QC and production activities internally. In addition to our manufacturing capabilities, MeiraGTx’s proprietary vector engineering and promoter platforms are enabling us to produce more potent vectors at lower doses, and our riboswitch technology provides us with an unprecedented control system for genetic medicines. These platform technologies give us potentially meaningful advantages in safety, efficacy and cost of goods across multiple programs.”

Recent Development Highlights and Anticipated Milestones

Botaretigene Sparoparvovec (AAV-RPGR) for the Treatment of XLRP:

- MeiraGTx and development partner Janssen Pharmaceuticals, Inc. (Janssen), one of the Janssen Pharmaceutical Companies of Johnson & Johnson, continue to enroll and dose patients in the Phase 3 Lumeos clinical trial.
- The Company will provide an update on the patients treated in the Phase 1/2 clinical trial of XLRP (MGT009), including the randomized expansion cohort of the study, during the second quarter of 2022, and MeiraGTx and Janssen intend to present the full data from this study at medical meetings later this year.

AAV-hAQP1 for the Treatment of Grade 2/3 Radiation-Induced Xerostomia:

- MeiraGTx intends to present data from all four cohorts (n=12) in the unilateral dose escalation Phase 1 AQUAx trial as well as data from the bi-lateral cohorts (n=12) in the fourth quarter of 2022.
- The Company is currently planning a randomized, double-blind, placebo-controlled Phase 2 study and expects to initiate this trial by the end of 2022.

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

- The Company is filing an Investigational New Drug (IND) application in May 2022 with material manufactured in its cGMP facility in London, United Kingdom.

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

- With development partner Janssen, MeiraGTx expects to initiate further clinical studies in 2022 for both AAV-CNGB3 and AAV-CNGA3 for the treatment of ACHM associated with mutations in the CNGB3 and CNGA3 genes.

Proprietary Promoter Platforms:

- MeiraGTx continues to expand its libraries of novel small, strong, synthetic promoters.
- MeiraGTx has generated *in-vivo* data in multiple tissues demonstrating significant increases in promoter strength and tissue specificity.

Riboswitch Gene Control Platform:

- MeiraGTx is advancing several small molecule candidates through IND-enabling studies with the aim of initiating first-in-human safety and tolerability studies by the end of 2022.
- Novel regulation platform can be used to precisely control gene expression in cell therapy, gene editing, with any gene and any vector with unprecedented dynamic range using an oral small molecule.

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

As of March 31, 2022, MeiraGTx had cash and cash equivalents of approximately $114 million, as well as approximately $13.1 million in receivables due from Janssen in the second quarter of 2022 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 the fourth quarter of 2023.

Financial Results

License revenue was $5.6 million for the three months ended March 31, 2022, compared to $4.6 million for the three months ended March 31, 2021. This increase represents increased amortization of the $100.0 million upfront payment as well as amortization of the $30.0 million milestone payment received in connection with the Janssen collaboration agreement.

General and administrative expenses were $11.3 million for the three months ended March 31, 2022, compared to $9.9 million for the three months ended March 31, 2021. The increase of $1.4 million was primarily due to an increase of $1.4 million in share-based compensation, $0.6 million in payroll and payroll-related costs and $0.3 million in consulting fees. These increases were partially offset by decreases of rent and facilities costs of $0.4 million due to additional

allocations to research and development, $0.3 million in insurance costs and $0.2 in legal and accounting fees.

Research and development expenses for the three months ended March 31, 2022 were $23.1 million, compared to $16.7 million for the three months ended March 31, 2021. The increase of $6.4 million was primarily due to an increase of $3.4 million in costs related to the manufacture of material for our clinical trials, $1.6 million in payroll and payroll-related costs, $1.4 million in share-based compensation, $1.4 million in costs related to our pre-clinical research and clinical trials, $1.3 million in rent and facilities costs, $0.3 million in depreciation and $0.1 million in other research and development costs. These increases were partially offset by a decrease of $1.6 million in license fees and an increase of $1.5 million in research funding provided under our collaboration agreement with Janssen.

Foreign currency loss was $2.6 million for the three months ended March 31, 2022 compared to a loss $1.6 million for the three months ended March 31, 2021. The change in the amount of $1.0 million was primarily due to a strengthening of the U.S. dollar against the pound sterling and euro during the three months ended March 31, 2022.

Net loss attributable to ordinary shareholders for the quarter ended March 31, 2022 was $31.0 million, or $0.70 basic and diluted net loss per ordinary share, compared to a net loss attributable to ordinary shareholders of $23.6 million, or $0.54 basic and diluted net loss per ordinary share for the quarter ended March 31, 2021.

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, and a transformative gene regulation platform technology which allows precise, dose responsive control of gene expression by oral small molecules with dynamic range that can exceed 5000-fold. 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 diseases, including both inherited retinal diseases as well as large degenerative ocular diseases, neurodegenerative diseases and severe forms of xerostomia. Though initially focusing on the eye, central nervous system, and salivary gland, MeiraGTx plans to expand its focus 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 2022 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, 2022, 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 Period Ended March 31,	
	2022	2021
License revenue - related party	$ 5,633	$ 4,595
Operating expenses:		
General and administrative	11,268	9,918
Research and development	23,099	16,709
Total operating expenses	34,367	26,627
Loss from operations	(28,734)	(22,032)
Other non-operating income (expense):		
Foreign currency loss	(2,647)	(1,615)
Interest income	16	89
Interest expense	(77)	(59)
Fair value adjustment	397	—
Net loss	(31,045)	(23,617)
Other comprehensive income (loss):		
Foreign currency translation gain (loss)	1,932	(271)
Total comprehensive loss	$ (29,113)	$ (23,888)
Net loss	$ (31,045)	$ (23,617)
Basic and diluted net loss per ordinary share	$ (0.70)	$ (0.54)
Weighted-average number of ordinary shares outstanding	44,501,314	43,974,395

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

	March 31, 2022	December 31, 2021
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 113,781	$ 137,703
Accounts receivable - related party	13,078	22,384
Prepaid expenses	7,217	8,102
Tax incentive receivable	6,865	12,634
Other current assets	1,984	2,420
Total Current Assets	142,925	183,243
Property, plant and equipment, net	84,069	75,860
Intangible assets, net	1,668	1,791
In-process research and development	772	783
Other assets	1,609	1,404
Equity method and other investments	6,656	6,656
Right-of-use assets - operating leases, net	23,223	22,782
Right-of-use assets - finance leases, net	26,771	27,645
TOTAL ASSETS	$ 287,693	$ 320,164
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 18,498	$ 15,348
Accrued expenses	23,181	27,586
Lease obligations, current	3,632	3,374
Deferred revenue - related party, current	20,190	21,820
Total Current Liabilities	65,501	68,128
Deferred revenue - related party	37,277	43,046
Lease obligations	20,767	20,359
Asset retirement obligations	2,114	2,081
Deferred income tax liability	194	196
Other long-term liabilities	556	953
TOTAL LIABILITIES	126,409	134,763
COMMITMENTS (Note 9)		
SHAREHOLDERS' EQUITY:		
Ordinary Shares, $0.00003881 par value, 1,288,327,750 authorized, 44,710,678 and 44,548,925 shares issued and outstanding at March 31, 2022 and December 31, 2021, respectively	2	2
Capital in excess of par value	533,655	528,659
Accumulated other comprehensive loss	(739)	(2,671)
Accumulated deficit	(371,634)	(340,589)
Total Shareholders' Equity	161,284	185,401
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 287,693	$ 320,164