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 14, 2023**

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 14, 2023, MeiraGTx Holdings plc (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 2023. 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 14, 2023.
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: November 14, 2023

MEIRAGTX HOLDINGS PLC

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

Exhibit 99.1

MeiraGTx Announces Third Quarter 2023 Financial and Operational Results

- *Received strategic investment from Sanofi purchasing $30 million of ordinary shares of the Company at a price of $7.50 per share in October 2023*

- *Announced a right of first negotiation (ROFN) with Sanofi for the use of MeiraGTx's Riboswitch gene regulation technology for certain Central Nervous System (CNS) and Immunology and Inflammation (I&I) targets, including IL-4 and IL-13, as well as for GLP-1 and other gut peptides for metabolic disease, and for MeiraGTx's Phase 2 Xerostomia program*

- *Enrollment in the Phase 2 randomized, double-blind, placebo-controlled study of AAV2-hAQP1 for the treatment of grade 2/3 radiation-induced Xerostomia (RIX) is ongoing*

- *Presented eight posters at the European Society of Gene and Cell Therapy (ESGCT) 2023 Annual Congress including data on proprietary RiboCAR platform and an oral presentation on amyotrophic lateral sclerosis (ALS) program*

- *Received a 2nd Commercial Manufacturer's/Importer's Authorization (MIA) for Quality Control (QC) testing at GMP manufacturing facility in Shannon, Ireland*

LONDON and NEW YORK, November 14, 2023 (GLOBE NEWSWIRE) -- MeiraGTx Holdings plc (Nasdaq: MGTX), a vertically integrated, clinical stage gene therapy company, today announced financial and operational results for the third quarter ended September 30, 2023, and provided a corporate update.

"We are very happy to now have Sanofi as one of our top shareholders," said Alexandria Forbes, Ph.D., president and chief executive officer of MeiraGTx. "Sanofi's interest in large market indications validates what MeiraGTx has been pioneering since inception of the Company – the use of genetic medicines and gene regulation to address large chronic diseases, not just rare inherited disorders. With our end-to-end manufacturing infrastructure and novel platform technologies, we are confident we can use our genetic medicines toolkit to treat much larger populations of patients without prohibitively high costs."

Dr. Forbes continued, "With our Phase 3 LUMEOS trial for X-linked retinitis pigmentosa (XLRP) fully enrolled and progressing towards BLA filing, we continue to focus on expediting the clinical development of our wholly-owned Xerostomia and Parkinson's programs as well as advancing our Riboswitch platform." In addition Dr. Forbes said, "As stated last month, in parallel with Sanofi's investment, due to the breadth of interest over the past several months from multiple parties around strategic transactions involving certain assets of the Company, we have engaged Evercore and Wachtell Lipton to work with management and our Board of

Directors to execute one or more of these potential strategic transactions to maximize value for our shareholders."

Recent Development Highlights and Anticipated Milestones

Strategic Investment from Sanofi:

- On October 30, 2023, Sanofi purchased $30 million of ordinary shares of the Company at a price of $7.50 per share.
- Sanofi received a right of first negotiation (ROFN) for the use of MeiraGTx's Riboswitch gene regulation technology for certain Central Nervous System (CNS) and Immunology and Inflammation (I&I) targets, including IL-4 and IL-13, as well as for GLP-1 and other gut peptides for obesity, and for MeiraGTx's Phase 2 Xerostomia program.

Bota-vec for the Treatment of XLRP:

- Enrollment completed in second quarter 2023 in the pivotal Phase 3 LUMEOS clinical trial in collaboration with Janssen Pharmaceuticals, Inc. (Janssen), a Johnson & Johnson company.
- In September 2023, the IND for bota-vec for the treatment of XLRP was transferred from MeiraGTx to Janssen.

AAV-hAQP1 for the Treatment of Grade 2/3 RIX:

- Initiated a Phase 2 randomized, double-blind, placebo-controlled study in June 2023 with participants currently being enrolled and dosed across multiple sites in the U.S. and Canada.
- Results from AQUAx Phase 1 open-label, dose-escalation study of gene therapy with AAV2-hAQP1 as a treatment for RIX and parotid gland hypofunction presented at ESGCT 2023 Annual Congress on October 26, 2023.

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

- The Company is dosing patients in the AAV-GAD clinical trial under a new IND with material manufactured from its cGMP facility in London, United Kingdom using MeiraGTx's proprietary production process.
- The AAV-GAD trial is a three-arm randomized Phase 1 clinical bridging study with subjects randomized to sham control or one of two doses of AAV-GAD.
- The objective of the AAV-GAD trial (NCT05603312) is to evaluate the safety and tolerability of AAV-GAD when delivered to the subthalamic nucleus (STN) of patients with Parkinson's disease.
- Completion of enrollment is anticipated in the fourth quarter of 2023.

ESGCT 2023 Annual Congress:

ALS and Frontotemporal Dementia (FTD) Program Oral Presentation:

- Presented preclinical efficacy of AAV-hUPF1 with an optimized vector genome and novel CNS capsid: Gene Therapy for ALS and FTD.

Poster Presentations:

- Presented eight posters, including Riboswitch Gene Regulation Platform:
  - RiboCAR-T cell activity can be precisely tuned and "remotely" controlled to improve the efficacy, durability, and safety of CAR-T cell therapy.
  - T cells with RiboCAR showed delayed exhaustion during expansion in the absence of small molecule inducer and enhanced target cell-stimulated T cell activation and anti-cancer cytotoxicity in the presence of small molecule inducer when compared with T cells constitutively expressing CAR.

Wholly-Owned Gene Therapy Manufacturing Facility in Shannon, Ireland Received 2nd Commercial MIA Authorization for QC Testing:

- The QC facility in Shannon, Ireland performs advanced biochemical quality control testing for release and stability testing for MeiraGTx's and its partner's programs.
- Unique in its scale and integrated capabilities and stretching over 150,000 square feet, the GMP Shannon facility is Ireland's first commercial-scale gene therapy manufacturing site and contains facilities for flexible and scalable viral vector production for clinical and commercial supply as well as a facility for plasmid DNA production in addition to the GMP licensed QC facility.

As of September 30, 2023, MeiraGTx had cash and cash equivalents of approximately $64 million, as well as approximately $22 million in receivables due from Janssen. Together with the $30 million investment from Sanofi on October 30, 2023, the Company believes that it will have sufficient capital to fund operating expenses and capital expenditure requirements into mid-2025.

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

Financial Results

Cash, cash equivalents and restricted cash were $64.4 million as of September 30, 2023, compared to $115.5 million as of December 31, 2022.

License revenue was $5.1 million for the quarter ended September 30, 2023, compared to $4.8 million for the quarter ended September 30, 2022. This increase represents increased amortization of the $100.0 million upfront payment as well as increased amortization of the $30.0 million milestone payment received in connection with the Janssen collaboration.

General and administrative expenses were $10.0 million for the three months ended September 30, 2023, compared to $10.8 million for the three months ended September 30, 2022. The decrease of $0.8 million was primarily due to a decrease in consulting fees, insurance costs, legal and accounting fees and an employee retention tax credit. These decreases were partially offset by increases in payroll and payroll-related costs, share-based compensation and other office related costs.

Research and development expenses were $27.9 million for the three months ended September 30, 2023, compared to $16.9 million for the three months ended September 30, 2022. The increase of $11.0 million was primarily due to an increase in manufacturing costs primarily due

to a decrease in the number of batches of clinical trial material produced during the three months ended September 30, 2023 compared to the three months ended September 30, 2022 which were charged to the clinical programs and a decrease in research funding provided under our Janssen collaboration. These increases were partially offset by decreases in expenses related to our preclinical programs primarily related to preclinical ocular diseases, clinical trial expenses primarily due to a decrease in the number of batches of clinical trial material produced in the three months ended September 30, 2023 compared to the three months ended September 30, 2022 and other research and development costs primarily related to an increase in the estimated research and development tax credit refund in the three months ended September 30, 2023 compared to a reduction in the three months ended September 30, 2022.

Foreign currency loss was $8.7 million for the three months ended September 30, 2023, compared to a loss of $12.8 million for the three months ended September 30, 2022. The unrealized losses were a result of a strengthening of the U.S. dollar against the pound sterling and euro as it relates to the quarterly valuation of our intercompany payables and receivables. The decrease in the loss of $4.2 million was primarily due to a smaller fluctuation in exchange rates during the three months ended September 30, 2023 compared to the three months ended September 30, 2022.

Net loss attributable to ordinary shareholders for the quarter ended September 30, 2023 was $44.3 million, or $0.74 basic and diluted net loss per ordinary share, compared to a net loss attributable to ordinary shareholders of $37.3 million, or $0.83 basic and diluted net loss per ordinary share for the quarter ended September 30, 2022.

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 that 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 our pre-clinical data and reporting of such data and the timing of results of data, Evercore's work

with management and our Board of Directors, the review or pursuit of any potential strategic transactions, the nature, timing or likelihood of any strategic transactions or announcements of any strategic transactions, the anticipated benefits of any strategic transactions and their expected impact on the Company's outlook, operations, opportunities, financial condition, business plan and overall strategy, 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, repay our debt obligations, identify additional and develop existing product candidates, successfully execute strategic transactions or 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, 2023, 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.

There can be no assurance that the review and evaluation of potential strategic transactions will result in any particular transaction or transactions or other strategic changes or outcomes and the timing of any such event is similarly uncertain. MeiraGTx does not intend to disclose or comment on developments related to the foregoing unless or until it determines that further disclosure is appropriate or required.

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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 September 30,		For the Nine-Month Period Ended September 30,	
	2023	2022	2023	2022
License revenue - related party	$ 5,103	$ 4,816	$ 11,977	$ 21,208
Operating expenses:				
General and administrative	10,009	10,762	35,169	32,548
Research and development	27,856	16,862	70,115	63,960
Total operating expenses	37,865	27,624	105,284	96,508
Loss from operations	(32,762)	(22,808)	(93,307)	(75,300)
Other non-operating income (expense):				
Foreign currency loss	(8,677)	(12,838)	(2,915)	(25,911)
Interest income	523	288	1,723	345
Interest expense	(3,381)	(1,892)	(9,796)	(2,051)
Fair value adjustment	—	(34)	53	615
Net loss	(44,297)	(37,284)	(104,242)	(102,302)
Other comprehensive (loss) income:				
Foreign currency translation gain	6,007	8,772	1,113	18,062
Comprehensive loss	$ (38,290)	$ (28,512)	$ (103,129)	$ (84,240)
Net loss	$ (44,297)	$ (37,284)	$ (104,242)	$ (102,302)
Basic and diluted net loss per ordinary share	$ (0.74)	$ (0.83)	$ (1.91)	$ (2.29)
Weighted-average number of ordinary shares outstanding	59,526,642	44,687,635	54,544,660	44,620,900

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

	September 30, 2023	December 31, 2022
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 63,365	$ 115,516
Accounts receivable - related party	22,398	21,334
Prepaid expenses	6,997	8,133
Tax incentive receivable	10,013	7,689
Other current assets	758	1,667
Total Current Assets	103,531	154,339
Property, plant and equipment, net	111,880	109,266
Intangible assets, net	1,140	1,335
In-process research and development	732	742
Restricted cash	1,038	—
Other assets	1,421	1,402
Equity method and other investments	6,326	6,326
Right-of-use assets - operating leases, net	17,446	20,109
Right-of-use assets - finance leases, net	23,680	24,718
TOTAL ASSETS	$ 267,194	$ 318,237
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 20,773	$ 16,616
Accrued expenses	28,251	39,818
Lease obligations, current	4,092	3,884
Deferred revenue - related party, current	7,922	15,123
Other current liabilities	2,476	6,631
Total Current Liabilities	63,514	82,072
Deferred revenue - related party	23,191	27,436
Lease obligations	14,256	17,331
Asset retirement obligations	2,319	2,179
Deferred income tax liability	184	186
Note payable, net	71,844	71,033
Other long-term liabilities	—	262
TOTAL LIABILITIES	175,308	200,499
COMMITMENTS AND CONTINGENCIES (Note 10)		
SHAREHOLDERS' EQUITY:		
Ordinary Shares, $0.00003881 par value, 1,288,327,750 authorized, 59,597,151 and 48,477,209 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	2	2
Capital in excess of par value	659,170	581,893
Accumulated other comprehensive income	7,160	6,047
Accumulated deficit	(574,446)	(470,204)
Total Shareholders' Equity	91,886	117,738
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 267,194	$ 318,237