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 10, 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 November 10, 2021, MeiraGTx Holdings plc (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 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 November 10, 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: November 10, 2021

MEIRAGTX HOLDINGS PLC

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

Exhibit 99.1

MeiraGTx Reports Third Quarter 2021 Financial and Operational Results

LONDON and NEW YORK, November 10, 2021 (GLOBE NEWSWIRE) -- MeiraGTx Holdings plc (Nasdaq: MGTX), a vertically integrated, clinical stage gene therapy company, today announced financial results for the third quarter ended September 30, 2021 and provided an update on recent progress.

During the quarter, MeiraGTx continued to progress the Phase 3 Lumeos Trial of botaretigene sparoparvovec, formerly referred to as AAV5-RPGR, in X-linked retinitis pigmentosa (XLRP) with its partner Janssen Pharmaceuticals, Inc. (Janssen), one of the Janssen Pharmaceutical Companies of Johnson & Johnson, with subjects currently screening. Data from the Phase 1/2 dose escalation study in RPGR patients presented at the EURETINA 2021 Virtual Meeting showed treatment with botaretigene sparoparvovec reverses the course of disease progression when retinal function assessed 12 months following treatment is compared with retinal function in these same subjects up to 48 months prior to treatment. The Company continues to successfully enroll subjects in its AQUAx Phase 1 study for treatment of Grade 2/3 radiation-induced xerostomia with 4 sites open and anticipates completing enrollment in the dose escalation phase of the study by the end of the year. The Company will provide a clinical update from the AQUAx study in early December. At the European Society of Gene and Cell Therapy (ESGCT) 2021 Annual Congress the Company presented data on its riboswitch gene regulation platform as well as data from two preclinical programs in ophthalmology targeting two different inherited retinal dystrophies, KCNV2 and GUCY2D.

“We continued to make significant progress this quarter advancing our clinical programs,” said Alexandria Forbes, Ph.D., President and Chief Executive Officer of MeiraGTx. “We are equally encouraged by the progress we have made in multiple preclinical programs, including several ophthalmology programs, our AAV-UPF1 program for ALS and our riboswitch gene regulation platform. We look forward to presenting the riboswitch gene regulation platform in further detail at our Research and Development Day in December.”

Third Quarter and Recent Corporate and Clinical Development Highlights

Botaretigene sparoparvovec for the Treatment of XLRP:

- Twelve-month clinical data from MeiraGTx’s Phase 1/2 dose-escalation phase of study (MGT009) of botaretigene sparoparvovec were presented as an oral presentation at the EURETINA 2021 Virtual Meeting in September.
    - The retinal function of ten adult males aged 18-30 years with RPGR-associated XLRP was assessed 12 months post-treatment in MGT009.
- For the intermediate dose-escalation cohort (N=4), intervention with botaretigene sparoparvovec in the poorer-seeing eye altered the course of natural disease progression.

- At 12 months post-intervention, mean retinal sensitivity (MS) and volumetric analysis of the central 30 degrees of the retinal field (V30) in the treated eye were similar to levels observed 24 months pre-intervention, while the untreated eye showed a continued downward trajectory.

Riboswitch Gene Regulation Platform:

- Data from the Company's riboswitch gene regulation platform was presented at the ESGCT 2021 Annual Congress demonstrating reversible regulation of gene expression to high dynamic range in mammalian cells and precise dose-responsive activation of transgene expression *in-vivo*.

Pre-clinical Programs for Inherited Retinal Diseases (IRDs):

Data on novel vector development for gene replacement therapies in Inherited Retinal Diseases was presented at the ESGCT 2021 Annual Congress in October.

- **AAV-KCNV2 Gene Therapy for Cone Dystrophy:**
  - Meira's novel vectors successfully delivered the *hKCNV2* gene to photoreceptors in retinal organoids following transduction, restoring protein expression in the correct subcellular location as well as native protein-to-protein interactions.
  - Transcriptomic analyses indicated disease correction at a deep transcriptional level, and that AAV-mediated *KCNV2* gene supplementation has the potential to benefit patients with cone dystrophies due to *KCNV2* mutations.

- **AAV-GUCY2D Gene Therapy for Cone Dystrophy:**
  - Meira's novel vectors improved quantitative expression levels of *GUCY2D* and PDE6β relative to non-transduced controls, and total cGMP levels in transduced GUCY2D KO (GUCY2D knockout) human retinal organoids were restored to close to those observed in healthy human retinal organoids, demonstrating vector potency and transgene function.
  - These results indicate that gene replacement in GUCY2D-deficient human retinal organoids restored protein expression and cGMP levels in transduced organoids.
  - This provides support for the potential use of AAV-mediated *GUCY2D* gene supplementation as a treatment for patients with inherited retinal dystrophy caused by mutations in *GUCY2D*.

Anticipated Upcoming Milestones and Corporate Activities

- Provide a clinical update of the Phase 1 AQUAx trial of AAV-AQP1 for the treatment of Grade 2/3 radiation-induced xerostomia in early December 2021.
- Complete enrollment of the Phase 1 AQUAx trial of AAV-AQP1 for the treatment for Grade 2/3 radiation-induced xerostomia during the fourth quarter of 2021.
- The Company will hold a Research and Development Day in December 2021 where additional data on its synthetic riboswitch gene regulation platform as well as the Company's proprietary promoter platforms will be presented.
- File an Investigational New Drug (IND) application for AAV-GAD for the treatment of Parkinson's Disease during the fourth quarter of 2021.
- Initiate, with Janssen, later stage clinical studies for AAV-CNGB3 and AAV-CNGA3 for the treatment of achromatopsia (ACHM) in 2022.

- Initiate a Phase 3 pivotal trial of AAV-RPE65 for patients with *RPE65*-associated retinal dystrophy in early 2022.

Financial Results

License revenue was $6.9 million for the quarter ended September 30, 2021, compared to $5.1 million for the quarter ended September 30, 2020. 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.

General and administrative expenses were $7.9 million for the quarter ended September 30, 2021, compared to $8.9 million for the quarter ended September 30, 2020. The decrease of $1.0 million was primarily due to a decrease in legal and accounting fees, rent and facilities costs due to additional allocations to research and development, insurance costs and payroll and payroll-related costs. These decreases were partially offset by increases in share-based compensation, consulting fees and other office related costs.

Research and development expenses were $21.6 million for the quarter ended September 30, 2021, compared to $4.6 million for the quarter ended September 30, 2020. The increase of $17.0 million was primarily due to an increase in costs related to pre-clinical research and clinical trials, costs related to the manufacture of material for clinical trials, payroll and payroll-related costs due to hiring in connection with the expansion of clinical trials and manufacturing capabilities, rent and facilities costs, depreciation, share-based compensation, license fees, other research and development costs and a reduction in the estimated research and development tax credit refunds. These increases were partially offset by an increase in research funding provided under the collaboration agreement with Janssen.

Foreign currency loss was $3.3 million for the quarter ended September 30, 2021, compared to a gain of $1.9 million for the quarter ended September 30, 2020. The change in the amount of $5.2 million was primarily due to a strengthening of the U.S. dollar against the pound sterling and euro during the three months ended September 30, 2021.

Net loss attributable to ordinary shareholders for the quarter ended September 30, 2021 was $25.9 million, or $0.59 basic and diluted net loss per ordinary share, compared to a net loss attributable to ordinary shareholders of $6.4 million, or $0.17 basic and diluted net loss per ordinary share for the quarter ended September 30, 2020.

As of September 30, 2021, MeiraGTx had cash and cash equivalents of approximately $143.6 million, as well as approximately $16.8 million due in receivables from Janssen, compared to $179.1 million as of September 30, 2020.

The Company believes it will have sufficient capital to fund operating expenses and capital expenditure requirements into the second quarter of 2023.

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 our pre-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 September 30, 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 September 30,		For the Nine-Month Periods Ended September 30,	
	2021	2020	2021	2020
License revenue - related party	$ 6,947	$ 5,092	$ 16,658	$ 11,775
Operating expenses:				
General and administrative	7,887	8,896	28,214	32,200
Research and development	21,612	4,626	53,512	28,911
Total operating expenses	29,499	13,522	81,726	61,111
Loss from operations	(22,552)	(8,430)	(65,068)	(49,336)
Other non-operating income (expense):				
Foreign currency (loss) gain	(3,366)	1,875	(4,600)	767
Interest income	32	158	188	1,141
Interest expense	(59)	(35)	(169)	(103)
Net loss	(25,945)	(6,432)	(69,649)	(47,531)
Other comprehensive income (loss):				
Foreign currency translation gain (loss)	2,669	(4,121)	1,991	342
Total comprehensive loss	$ (23,276)	$ (10,553)	$ (67,658)	$ (47,189)
Net loss	$ (25,945)	$ (6,432)	$ (69,649)	$ (47,531)
Basic and diluted net loss per ordinary share	$ (0.59)	$ (0.17)	$ (1.58)	$ (1.29)
Weighted-average number of ordinary shares outstanding	44,170,299	37,223,375	44,094,873	36,940,372

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

	September 30, 2021	December 31, 2020
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 143,634	$ 209,520
Accounts receivable - related party	16,775	38,479
Prepaid expenses	8,840	7,082
Tax incentive receivable	5,383	12,930
Other current assets	2,299	4,565
Total Current Assets	176,931	272,576
Property and equipment, net	63,699	44,042
Intangible assets, net	1,861	2,119
In-process research and development	803	852
Security deposits	1,166	812
Other assets	201	214
Equity method and other investments	6,665	—
Right-of-use assets	52,010	43,082
TOTAL ASSETS	$ 303,336	$ 363,697
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 11,421	$ 7,134
Accrued expenses	21,926	20,861
Lease obligations, current	3,280	2,583
Deferred revenue - related party, current	23,003	23,545
Other current liabilities	—	24
Total Current Liabilities	59,630	54,147
Deferred revenue - related party	32,488	49,297
Lease obligations	21,262	19,666
Asset retirement obligations	1,916	1,814
Deferred income tax liability	201	214
TOTAL LIABILITIES	115,497	125,138
COMMITMENTS (Note 10)		
SHAREHOLDERS' EQUITY:		
Ordinary Shares, $0.00003881 par value, 1,288,327,750 authorized, 44,316,385 and 44,189,150 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	2	2
Capital in excess of par value	521,420	504,482
Accumulated other comprehensive loss	(2,906)	(4,897)
Accumulated deficit	(330,677)	(261,028)
Total Shareholders' Equity	187,839	238,559
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 303,336	$ 363,697