**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 11, 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 August 11, 2022, MeiraGTx Holdings plc (the "Company") issued a press release announcing its financial results for the quarter ended June 30, 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 August 11, 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: August 11, 2022

MEIRAGTX HOLDINGS PLC

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

**MeiraGTx Reports Second Quarter 2022 Financial and Operational Results**

*-- Recent Positive Topline Data from the Phase 1/2 Trial of Botaretigene Sparoparvovec (AAV-RPGR) for the Treatment of X-linked Retinitis Pigmentosa (XLRP)*

*-- Financing Secured by Manufacturing Facilities Extends Cash Runway to Fourth Quarter 2024*

LONDON and NEW YORK, August 11, 2022 (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, 2022, and provided an update on recent progress.

“Over the past quarter we have continued to advance our gene therapy programs and platforms, including the recently announced positive topline data from the Phase 1/2 clinical study demonstrating that our investigational gene therapy, botaretigene sparoparvovec, has the potential to improve vision in patients with retinitis pigmentosa,” said Alexandria Forbes, Ph.D., president, and chief executive officer of MeiraGTx. “We look forward to presenting additional data from this study at the American Academy of Ophthalmology (AAO) annual meeting this year as we continue to enroll the pivotal Phase 3 Lumeos clinical trial of botaretigene sparoparvovec with our partner Janssen.”

Dr. Forbes continued, “We also recently announced a financing of up to $100 million with one of our largest shareholders, extending our cash runway to the fourth quarter of 2024. Our wholly-owned manufacturing facilities collateralized this transaction, enabling us to access minimally dilutive capital while retaining the significant and growing value of our proprietary programs and transformative genetic medicine platforms.”

**Recent Highlights and Anticipated Milestones**

**Botaretigene Sparoparvovec for the Treatment of XLRP:**

- In June 2022, MeiraGTx announced positive topline data from the MGT009 Phase 1/2 clinical trial of botaretigene sparoparvovec (formerly referred to as AAV-RPGR) for the treatment of patients with XLRP with disease-causing variants in the *RPGR* gene.
- Treatment with botaretigene sparoparvovec was found to be generally safe and well-tolerated, with no dose-limiting events.
- Significant improvements were demonstrated in multiple endpoints across each of the three domains of vision -- retinal function, visual function, and functional vision -- in patients treated with botaretigene sparoparvovec when compared to the randomized untreated control arm of the study at 6 months post-treatment.
- Full MGT009 data will be presented at the AAO annual meeting, being held September 30 – October 3, 2022, in Chicago, IL.
- The Company is currently enrolling patients in the Phase 3 Lumeos clinical trial of botaretigene sparoparvovec and targeting a Biologics License Application (BLA) filing in 2024.
- MeiraGTx and Janssen Pharmaceuticals, Inc. (Janssen), one of the Janssen Pharmaceutical Companies of Johnson & Johnson, are jointly developing botaretigene

sparoparvovec as part of a broader collaboration to develop and commercialize gene therapies for the treatment of inherited retinal diseases.

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

- Development partner Janssen plans to initiate a Phase 2b clinical trial for the treatment of ACHM associated with mutations in the *CNGB3* gene in 2022 followed by a Phase 2b clinical trial for the treatment of ACHM associated with mutations in the *CNGA3* gene in early 2023.
- Both ACHM clinical trials to be initiated by Janssen will use material manufactured at MeiraGTx's cGMP facility in London, United Kingdom.

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

- MeiraGTx plans to present data from all four cohorts (n=12) in the unilateral dose escalation Phase 1 AQUAx trial as well as data from the bilateral cohorts (n=12) in the fourth quarter of 2022.
- The Company plans to initiate a randomized, double-blind, placebo-controlled Phase 2 study by the end of 2022 with material manufactured in its cGMP facility in London, United Kingdom.

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

- The Company expects to initiate enrollment in its study of AAV-GAD during the second half of 2022 with material manufactured in its cGMP facility in London, United Kingdom.

**Gene Control Platforms:**

- The Company will present new data from its gene regulation platforms at medical meetings in the second half of 2022.
- MeiraGTx is advancing several small molecule candidates from its gene regulation platform with the aim of initiating first-in-human safety and tolerability studies this year.
- 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.

**Financing Agreement with Perceptive for Up to $100 Million:**

- In August 2022, MeiraGTx and Perceptive announced a senior secured financing arrangement for up to $100 million secured by MeiraGTx's wholly-owned manufacturing facilities in London, United Kingdom and Shannon, Ireland.
- The Company received $75 million upon closing and may request an additional $25 million during the first two years of the term under the same terms and collateral, subject to the lender's approval.

In addition to the $75.0 million gross proceeds from this recent financing, the Company had cash and cash equivalents of approximately $72.1 million as of June 30, 2022, as well as approximately $15.9 million in receivables due from Janssen from the second quarter of 2022. The Company believes it will have sufficient capital to fund operating expenses and capital expenditure requirements into the fourth quarter of 2024.

**Financial Results**

License revenue was $10.8 million for the three months ended June 30, 2022, compared to $5.1 million for the three months ended June 30, 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 Collaboration Agreement.

General and administrative expenses were $10.5 million for the three months ended June 30, 2022, compared to $10.4 million for the three months ended June 30, 2021. The increase of $0.1 million was primarily due to an increase of $1.0 million in share-based compensation, $0.4 million in legal and accounting fees, $0.1 million in depreciation and $0.2 million in other office related costs. These increases were partially offset by decreases of rent and facilities costs of $0.9 million due to additional allocations to research and development, $0.4 million in insurance costs and $0.3 million in payroll and payroll-related costs.

Research and development expenses for the three months ended June 30, 2022 were $24.0 million, compared to $15.2 million for the three months ended June 30, 2021. The increase of $8.8 million was primarily due to an increase of $2.2 million in payroll and payroll-related costs, $1.9 million in costs related to the manufacture of material for the Company's clinical trials, $1.1 million in share-based compensation, $1.0 million in rent and facilities costs, $0.4 million in costs related to the Company's pre-clinical research and clinical trials, $0.2 million in other research and development costs and a decrease of $2.3 million in research funding provided under the Collaboration Agreement with Janssen. These increases were partially offset by a decrease of $0.2 million in license fees and $0.1 million in depreciation.

Foreign currency loss was $10.4 million for the three months ended June 30, 2022 compared to a gain of $0.4 million for the three months ended June 30, 2021. The change in the amount of $10.8 million was primarily due to an unrealized loss on the quarterly valuation of the Company's intercompany payables and receivables due to the strengthening of the U.S. dollar against the pound sterling and euro during the three months ended June 30, 2022.

Net loss attributable to ordinary shareholders for the quarter ended June 30, 2022 was $34.0 million, or $0.76 basic and diluted net loss per ordinary share, compared to a net loss attributable to ordinary shareholders of $20.1 million, or $0.46 basic and diluted net loss per ordinary share for the quarter ended June 30, 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, repay our debt obligations, 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, 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.

**Contacts**

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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 June 30, | | For the Six-Month Period Ended June 30, | |
|---|---|---|---|---|
| | 2022 | 2021 | 2022 | 2021 |
| License revenue - related party | $ 10,759 | $ 5,116 | $ 16,392 | $ 9,711 |
| Operating expenses: | | | | |
| General and administrative | 10,518 | 10,409 | 21,786 | 20,327 |
| Research and development | 23,999 | 15,190 | 47,098 | 31,900 |
| Total operating expenses | 34,517 | 25,599 | 68,884 | 52,227 |
| Loss from operations | (23,758) | (20,483) | (52,492) | (42,516) |
| Other non-operating income (expense): | | | | |
| Foreign currency (loss) gain | (10,426) | 381 | (13,073) | (1,234) |
| Interest income | 41 | 67 | 57 | 156 |
| Interest expense | (82) | (51) | (159) | (110) |
| Fair value adjustment | 252 | — | 649 | — |
| Net loss | (33,973) | (20,086) | (65,018) | (43,704) |
| Other comprehensive income (loss): | | | | |
| Foreign currency translation gain (loss) | 7,357 | (407) | 9,290 | (678) |
| Total comprehensive loss | $ (26,616) | $ (20,493) | $ (55,728) | $ (44,382) |
| Net loss | $ (33,973) | $ (20,086) | $ (65,018) | $ (43,704) |
| Basic and diluted net loss per ordinary share | $ (0.76) | $ (0.46) | $ (1.46) | $ (0.99) |
| Weighted-average number of ordinary shares outstanding | 44,668,240 | 44,137,773 | 44,585,239 | 44,056,535 |

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

| | June 30, 2022 | December 31, 2021 |
|---|---|---|
| ASSETS | | |
| CURRENT ASSETS: | | |
| Cash and cash equivalents | $ 72,108 | $ 137,703 |
| Accounts receivable - related party | 15,942 | 22,384 |
| Prepaid expenses | 6,682 | 8,102 |
| Tax incentive receivable | 6,350 | 12,634 |
| Other current assets | 3,330 | 2,420 |
| Total Current Assets | 104,412 | 183,243 |
| | | |
| Property, plant and equipment, net | 91,388 | 75,860 |
| Intangible assets, net | 1,474 | 1,791 |
| In-process research and development | 723 | 783 |
| Other assets | 1,505 | 1,404 |
| Equity method and other investments | 6,656 | 6,656 |
| Right-of-use assets - operating leases, net | 21,538 | 22,782 |
| Right-of-use assets - finance leases, net | 24,765 | 27,645 |
| TOTAL ASSETS | $ 252,461 | $ 320,164 |
| | | |
| LIABILITIES AND SHAREHOLDERS' EQUITY | | |
| CURRENT LIABILITIES: | | |
| Accounts payable | $ 18,111 | $ 15,348 |
| Accrued expenses | 23,572 | 27,586 |
| Lease obligations, current | 3,634 | 3,374 |
| Deferred revenue - related party, current | 21,205 | 21,820 |
| Other current liabilities | 983 | — |
| Total Current Liabilities | 67,505 | 68,128 |
| | | |
| Deferred revenue - related party | 21,337 | 43,046 |
| Lease obligations | 19,063 | 20,359 |
| Asset retirement obligations | 2,099 | 2,081 |
| Deferred income tax liability | 181 | 196 |
| Other long-term liabilities | 304 | 953 |
| TOTAL LIABILITIES | 110,489 | 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 June 30, 2022 and December 31, 2021, respectively | 2 | 2 |
| Capital in excess of par value | 540,958 | 528,659 |
| Accumulated other comprehensive income (loss) | 6,619 | (2,671) |
| Accumulated deficit | (405,607) | (340,589) |
| Total Shareholders' Equity | 141,972 | 185,401 |
| TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY | $ 252,461 | $ 320,164 |