
**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): **February 13, 2024**

MeiraGTx Holdings plc

(Exact name of registrant as specified in its charter)

Cayman Islands
(State or other jurisdiction of incorporation or
organization)

001-38520
(Commission File Number)

98-1448305
(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, \$0.0003881 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 8.01. Other Events.

On February 13, 2024, MeiraGTx Holdings plc (the “Company”) issued a press release announcing the achievement of the \$50 million milestone under the asset purchase agreement the Company entered into with Janssen Pharmaceuticals, Inc. (J&J), a Johnson & Johnson company, in December 2023 relating to botaretigene sparoparvovec (*bota-vec*, formerly AAV-RPGR) for the treatment of X-linked retinitis pigmentosa (XLRP). 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.

Item 9.01. Financial Statements and Exhibits.

- (d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release of MeiraGTx Holdings plc, dated February 13, 2024.
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: February 13, 2024

MEIRAGTX HOLDINGS PLC

By: /s/ Richard Giroux

Name: Richard Giroux

Title: Chief Financial Officer and Chief Operating Officer



MeiraGTx Announces \$50 Million Milestone from Janssen Pharmaceuticals

- *MeiraGTx to receive \$50 million milestone after initiation of the extension study for the Phase 3 LUMEOS clinical trial for botaretigene sparoparvovec (bota-vec, formerly AAV-RPGR) for the treatment of X-linked retinitis pigmentosa (XLRP)*

LONDON and NEW YORK, February 13, 2024 (GLOBE NEWSWIRE) -- MeiraGTx Holdings plc (Nasdaq: MGTX), a vertically integrated, clinical stage gene therapy company, today announced the achievement of the first milestone under the asset purchase agreement the Company entered into with Janssen Pharmaceuticals, Inc. (J&J), a Johnson & Johnson company, in December 2023 relating to *bota-vec* for the treatment of XLRP.

“We are very happy to announce that the LUMEOS extension study has been initiated, which triggered the \$50 million milestone payment to MeiraGTx under the asset purchase agreement with J&J,” said Alexandria Forbes, Ph.D., president and chief executive officer of MeiraGTx.

Agreements related to *bota-vec*:

- MeiraGTx anticipates receiving an additional \$15 million in near-term milestone payments later in 2024.
- The Company will receive up to a further \$285 million upon first commercial sales of *bota-vec* in the U.S. and EU and for manufacturing technology transfer.
- MeiraGTx also entered into a commercial supply agreement with J&J for *bota-vec* manufacturing, which the Company anticipates will generate additional revenue during the product launch.

About MeiraGTx

MeiraGTx (Nasdaq: MGTX) is a vertically integrated, clinical-stage gene therapy company with a broad pipeline of late stage clinical programs supported by end-to-end manufacturing capabilities. MeiraGTx has an internally developed manufacturing platform process, internal plasmid production for GMP, two GMP viral vector production facilities as well as an in-house Quality Control hub for stability and release, all fit for IND through commercial supply. MeiraGTx has core capabilities in viral vector design and optimization and a transformative Riboswitch gene regulation platform technology that allows precise, dose-responsive control of gene expression by oral small molecules. MeiraGTx is focusing the Riboswitch platform on delivery of metabolic peptides including GLP-1, GIP, Glucagon and PYY using oral small molecules, as well as cell therapy for autoimmune disease. Although initially focusing on the eye, central nervous system, and salivary gland, MeiraGTx has developed the technology to apply genetic medicine to more common diseases, increasing efficacy, addressing novel targets, and expanding access in some of the largest disease areas where the unmet need remains great.



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, our ability to manufacture product candidates, potential milestone payments and the achievement of such milestones, including the receipt of the near-term milestone payments and the impact on our cash runway, and our pre-clinical data and reporting of such data and the timing of results of data, 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 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.



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