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): **December 20, 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 1.01 Entry into a Material Definitive Agreement.

Asset Purchase Agreement

On December 20, 2023 (the "Closing Date"), MeiraGTx Holdings plc (the "Company") and its wholly-owned subsidiary MeiraGTx UK II Limited, a company incorporated in England and Wales ("MeiraGTx UK II" and together with the Company, collectively the "Seller") entered into and consummated an Asset Purchase Agreement (the "Asset Purchase Agreement") with Janssen Pharmaceuticals, Inc., a Pennsylvania corporation ("Buyer"), pursuant to which Seller sold and assigned to Buyer, and Buyer purchased and assumed, that certain License Agreement, dated February 5, 2019, by and between UCL Business Plc (now UCL Business Ltd.), on the one hand, and MeiraGTx UK II and MeiraGTx Limited, on the other hand (the "UCL License Agreement"), relating to the research, development, manufacture and exploitation of Seller's gene therapy product for the treatment of X-linked retinitis pigmentosa related to mutations in the RPGR gene (the "RPGR Product"), and other related assets as described in the Asset Purchase Agreement.

In connection with the Seller and Buyer entering into the Asset Purchase Agreement, Buyer and MeiraGTx UK II entered into a Supply Agreement on the Closing Date pursuant to which MeiraGTx UK II agreed to manufacture and supply the RPGR Product for Buyer (the "Supply Agreement"). Under the Supply Agreement, MeiraGTx UK II, together with its affiliates, will manufacture commercial supply of the RPGR Product for Buyer for an initial term of four years, with Buyer having an option to extend the Supply Agreement for a fifth year upon written notification to Seller.

Buyer agreed to pay an upfront cash purchase price of $65,000,000 to Seller. Additionally, pursuant to and subject to the terms and conditions set forth in the Asset Purchase Agreement, Buyer agreed to pay Seller future contingent consideration of up to an aggregate of $350,000,000, as follows: (i) $50,000,000 upon initiation of the extension study for the Phase 3 LUMEOS clinical trial for the RPGR Product; (ii) $10,000,000 upon completion of certain specified development services for the drug substance for the RPGR Product; (iii) $5,000,000 upon completion of certain specified development services for the drug product for the RPGR Product; (iv) $175,000,000 upon the first commercial sale of an RPGR Product in the United States; (v) $75,000,000 upon the first commercial sale of an RPGR Product in at least one of the United Kingdom, France, Germany, Spain and Italy; (vi) $25,000,000 upon completion of the transfer of certain manufacturing technology for drug substance and drug product from Seller to Buyer; and (vii) $10,000,000 upon regulatory approval of a Buyer-selected manufacturing facility in each of the United States and European Union for commercial manufacture of the RPGR Product. Buyer will also be responsible for any royalty or milestone amounts that become payable on the RPGR Product under the UCL License Agreement.

Based on the Company's current cash and cash equivalents and initial $130 million upfront and near-term milestone payments expected pursuant to the Asset Purchase Agreement, the Company estimates that it will be able to fund its operating expenses and capital expenditure requirements into mid-2026. The Company has based these estimates on assumptions that may prove to be wrong, and could utilize available capital resources sooner than expected.

The Asset Purchase Agreement contains customary representations, warranties, and covenants from each of Seller and Buyer, including provisions that require Seller to indemnify Buyer and its affiliates and representatives against certain losses related to, among other things, breaches of Sellers' representations, warranties, covenants, and agreements as well as any excluded liabilities or excluded assets, as described in the Asset Purchase Agreement. Similarly, subject to certain customary limitations, Buyer agreed to indemnify Seller and their respective affiliates and representatives against certain losses related to, among other things, breaches of Buyer's representations, warranties, covenants, and agreements as well as the assumed liabilities and any use of the Licensed Intellectual Property (as defined below) by or on behalf of Buyer.

The Asset Purchase Agreement includes a grant by Seller, on behalf of itself and its Affiliates, to Buyer of a non-exclusive, perpetual, irrevocable, non-transferable (subject to the terms of the Asset Purchase Agreement), royalty-free, fully paid-up, worldwide license (with the right to grant sublicenses through multiple tiers, subject to the terms and provisions of the Asset Purchase Agreement) under certain know-how and patents that are owned or otherwise controlled by Seller or its affiliates as of the Closing and are necessary or reasonably useful for the exploitation of the

RPGR Product (the "Licensed Intellectual Property"), solely to research, develop, manufacture, commercialize and otherwise exploit any RPGR Product throughout the world.

Pursuant to the Asset Purchase Agreement, each of Seller and Buyer, on behalf of itself and its affiliates, agreed not to solicit or encourage any employee or consultant of the other party or its affiliates to terminate or diminish its relationship with such party or its affiliates for a period of five years after the Closing Date

Johnson & Johnson Innovation – JJDC, Inc., the investment arm of Johnson and Johnson and owner of Buyer, owns more than 10% of the Company's outstanding shares.

Consent and Amendment

On December 20, 2023, the Company, as issuer, and its wholly-owned subsidiaries MeiraGTx UK II and MeiraGTx Ireland DAC, a designated activity company limited by shares incorporated in Ireland ("MeiraGTx Ireland," and together with MeiraGTx UK II, the "Subsidiary Guarantors"), entered into a Consent and Amendment to Amended and Restated Notes Purchase Agreement and Guaranty (the "Consent and Amendment") by and among the Company, the Subsidiary Guarantors, the noteholders and other parties from time to time party thereto, and Perceptive Credit Holdings III, LP, as administrative agent and noteholder ("Perceptive"). The Consent and Amendment amends the Amended and Restated Notes Purchase Agreement and Guaranty, dated December 19, 2022, between the Company, the Subsidiary Guarantors, the noteholders and other parties from time to time party thereto, and Perceptive (as amended by that certain Consent and Amendment, dated August 10, 2023, the "Notes Purchase Agreement").

Under the Consent and Amendment, Perceptive has consented to the RPGR Program Transaction (as defined below) in accordance with the terms of the Notes Purchase Agreement. The Notes Purchase Agreement was also amended to increase the applicable early redemption fee (as defined and further described under the Consent and Amendment).

Ellen Hukkelhoven, Ph.D., a member of the Company's Board of Directors, is Head of Biotechnology Investments at Perceptive Advisors, LLC, an affiliate of Perceptive. Additionally, affiliates of Perceptive own, in the aggregate, more than 10% of the Company's outstanding shares.

Item 1.02 Termination of a Material Definitive Agreement.

In connection with the Seller and Buyer entering into the Asset Purchase Agreement described in Item 1.01 of this Current Report on Form 8-K, which description is incorporated by reference into this Item 1.02, Seller and Buyer entered into a Termination Agreement on December 20, 2023 (the "Termination Agreement", and together with the "Asset Purchase Agreement" and the Related Documents, the "RPGR Program Transaction") terminating that certain Collaboration, Option and License Agreement, dated as of January 30, 2019, by and among Seller and Buyer, as further amended by that certain First Amendment to Collaboration, Option and License Agreement, dated as of December 16, 2021 (the "Collaboration Agreement").

Item 2.01 Completion of Acquisition or Disposition of Assets.

The information described in Item 1.01 regarding the Asset Purchase Agreement is incorporated by reference into this Item 2.01.

Item 2.03 Creation of a Direct Financial Obligation or an Obligation under an Off-Balance Sheet Arrangement of a Registrant.

The information described in Item 1.01 regarding the financial obligations under the Consent and Amendment and the Notes Purchase Agreement is incorporated by reference into this Item 2.03.

Item 7.01 Regulation FD Disclosure.

On December 21, 2023, the Company issued a press release in connection with entering into the Asset Purchase Agreement, a copy of which is filed as Exhibit 99.1 and incorporated by reference into this Item 7.01.

The information in this Item 7.01 of this Current Report on Form 8-K 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.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this Current Report 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 $130 million upfront and 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 Current Report. Any such forward-looking statements represent management's estimates as of the date of this Current Report. 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 Current Report.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Press Release of MeiraGTx Holdings plc, dated as of December 21, 2023.
104	Cover Page Interactive Data File (the cover page XBRL tags are embedded in the Inline XBRL document).

SIGNATURES

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.

Dated: December 21, 2023

MEIRAGTX HOLDINGS PLC

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

Exhibit 99.1

MeiraGTx Announces Asset Purchase Agreement Involving its AAV-RPGR Collaboration for up to $415 million

- *MeiraGTx enters into an Asset Purchase Agreement related to botaretigene sparoparvovec (bota-vec, formerly AAV-RPGR) for the treatment of X-linked retinitis pigmentosa (XLRP) for a total of up to $415 million*

- *MeiraGTx to receive $130 million in upfront and near-term milestone payments as part of the agreement*

- *MeiraGTx to receive up to an additional $285 million upon first commercial sales of bota-vec in U.S. and EU and manufacturing technology transfer*

LONDON and NEW YORK, December 21, 2023 (GLOBE NEWSWIRE) -- MeiraGTx Holdings plc (Nasdaq: MGTX), a vertically integrated, clinical stage gene therapy company, today announced an asset purchase agreement with Janssen Pharmaceuticals, Inc. (J&J), a Johnson & Johnson company, for the remaining interests in *bota-vec* for the treatment of XLRP, as well as a commercial supply agreement and a technology transfer agreement for *bota-vec* manufacturing.

"We are very happy to announce the execution of the agreements related to *bota-vec* for the treatment of XLRP, which provide us with significant near-term cash as well as cash upon potential approval and commercialization of this important gene therapy, and additional revenue from the commercial manufacture of *bota-vec*," said Alexandria Forbes, Ph.D., president and chief executive officer of MeiraGTx. "The initial $130 million upfront and near-term milestone payments, combined with the $30 million investment we received from Sanofi in October, increases our cash runway to mid-2026, without including the additional $285 million in potential payments associated with this transaction."

Dr. Forbes continued, "This puts us in a strong financial position and allows us to increase our focus on our two late-stage clinical programs in Xerostomia and Parkinson's disease and our leading end-to-end manufacturing capabilities, with potential strategic activities around each of these wholly-owned assets. In addition, we continue to expedite the development of our Riboswitch gene regulation platform prioritizing targets in metabolic disease, immunology and oncology, which we believe have the potential to significantly alter outcomes in these broad disease areas and include several areas of interest from Sanofi following their investment earlier this quarter."

Agreements related to *bota-vec*:

- MeiraGTx to monetize potential future royalties and milestones related to *bota-vec* with J&J acquiring remaining rights for development, manufacturing, and commercialization of *bota-vec*.

- MeiraGTx to receive $130 million in upfront and near-term milestone payments, including $65 million at signing, an additional $50 million anticipated in the first quarter of 2024, with the remaining $15 million in milestone payments expected later in 2024.
- The Company will receive up to an additional $285 million in cash payments upon first commercial sales of *bota-vec* in the U.S. and EU and for manufacturing technology transfer.
- J&J will be responsible for any royalty or milestone amounts that become payable on *bota-vec* to UCL Business plc (University College London).
- MeiraGTx has also entered into a commercial supply agreement with J&J for *bota-vec* manufacturing.

Evercore Group L.L.C. is serving as financial advisor and Morgan Lewis & Bockius LLP is serving as legal advisor to MeiraGTx.

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

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
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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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