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): **April 16, 2026**

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.)

655 Third Avenue, Suite 1115
New York, NY 10017
(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 7.01 Regulation FD Disclosure.

On April 16, 2026, MeiraGTx Holdings plc (the "Company") issued a press release announcing 3-year data from the Company's Phase 1 AQUAx clinical study of AAV-hAQP1 for the treatment of grade 2/3 radiation induced xerostomia, 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 (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 8.01 Other Events.

Recent Developments

On April 16, 2026, the Company announced positive 3-year data from the Company's Phase 1 AQUAx clinical study of AAV-hAQP1 for the treatment of grade 2/3 radiation induced xerostomia.

Treatment was observed to be safe and well tolerated at each dose tested with no dose-limiting toxicity or treatment-related serious adverse events.

Results from Xerostomia Questionnaire ("XQ")

Change from Baseline to Month 12 Maintained through Month 36

- Unilateral: 7/12 (58%) had score improvements (decrease) ≥8 at 12 months
- Bilateral: 9/12 (75%) had score improvements ≥8 at 12 months
- Overall, at 12 months, 63% of participants achieved at least a 10-point improvement in XQ
- The improvement in XQ score observed at 12 months was maintained through 36 months with 62% of participants reporting at least a 10-point improvement

Average Change from Baseline to Month 12 Maintained through Month 36

- In unilaterally treated participants, an average 13-point improvement from baseline in XQ was seen at 12 months
- In bilaterally treated participants, an average 21-point improvement from baseline in XQ was seen at 12 months
- Overall, at 12 months, an average 17-point improvement from baseline was observed
- The 17-point improvement in XQ score observed at 12 months was maintained through 36 months

Results from Unstimulated Whole Saliva Flow Rate ("UWSFR")

Improvement from Baseline to Month 12 Maintained through Month 36

- Overall, the UWSFR improved to an average of 0.36 mL/min at 12 months, within the normal range (0.3-0.4 mL/min)
- The normalization in UWSFR observed at 12 months was maintained through 36 months with an average of 0.34 mL/min

The Company believes AAV-hAQP1 represents a significant commercial opportunity as a potential first-in-class, disease-modifying therapy for late, moderate-to-severe radiation-induced xerostomia (RIX), a severe, lifelong condition with no effective treatments. Persistent RIX affects an estimated 165,000 patients in the United States and approximately 435,000 patients globally, with ~48,000 new cases globally across major markets. Market research incorporating our three-year durability data demonstrated extremely strong physician enthusiasm, with approximately 78% clinician-stated preference translating to ~52% projected usage after adjustment, alongside favorable payor perceptions and an estimated ~90% U.S. market access coverage. Based on primary market research commissioned by the Company, the Company estimates peak global annual revenue potential of approximately $3.7 billion, with a steady state estimate of approximately $3.2 billion annually in the late 2030s. In the U.S. alone, this translates to estimated peak annual revenue of approximately $2.0 billion, with a steady state of approximately $1.8 billion annually in the late 2030s. These estimates are supported by a concentrated U.S. treatment landscape enabling efficient access to a majority of eligible patients through a focused set of major treatment centers.

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 the number of patients with RIX, the market size for AAV-hAQP1, market access coverage, physician adoption, and potential global sales, as well as statements that include the words “expect,” “will,” “intend,” “plan,” “believe,” “project,” “forecast,” “estimate,” “may,” “could,” “should,” “would,” “continue,” “anticipate,” “eligible” 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 or rare pediatric disease designations, retain key personnel or attract qualified employees, or incur expected levels of operating expenses; the impact of pandemics, epidemics or outbreaks of infectious diseases 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 Annual Report on Form 10-K for the year ended December 31, 2025, 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 April 16, 2026.
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: April 16, 2026

MEIRAGTX HOLDINGS PLC

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

MeiraGTx Announces Positive Three-year Data from the Phase 1 AQUAx Clinical Study of AAV-hAQP1 for the Treatment of Grade 2/3 Late Radiation-Induced Xerostomia

- *Clinically meaningful improvements in xerostomia symptoms measured by PRO Xerostomia Questionnaire (XQ) maintained out to 3 years post treatment with AAV-hAQP1 for both bilateral and unilateral cohorts*

- *Increases in Unstimulated Whole Saliva Flow Rate (UWSFR) maintained out to 3 years*

- *AAV-hAQP1 was safe and well tolerated at each dose tested*

- *AAV-hAQP1 Data presentation webcast to be held today, April 16, 2026, at 8:00 a.m. ET*

LONDON and NEW YORK, April 16, 2026 (GLOBE NEWSWIRE) -- MeiraGTx Holdings plc (NASDAQ: MGTX), a vertically integrated, clinical-stage genetic medicines company, today announced positive three-year data from the completed Phase 1 AQUAx study of AAV-hAQP1 for the treatment of grade 2/3 late radiation-induced xerostomia (RIX).

“Today we are very pleased to be releasing 3-year data from the Phase 1 AQUAx study which includes the full 36-month data from all cohorts,” said Alexandria Forbes, Ph.D., president and chief executive officer of MeiraGTx. “The 3-year data shows remarkable maintenance of the unprecedented improvements seen in response to AAV-hAQP1 treatment at 12 months. XQ responses are maintained over 3 years as is unstimulated saliva flow – the objective measure of the therapy’s mechanism of action. The durability we are seeing with AAV-hAQP1 is extraordinary, particularly following the simple one-time treatment. In addition to the durability of the population data over three years, the consistency of responses within individual patients is also encouraging. This three-year durability data is changing the way AAV-hAQP1 treatment is viewed by physicians, as it is now being regarded as a simple one-time treatment that has disease modifying impact on patients with this lifelong, severely debilitating condition that has no other treatments.”

Dr. Forbes continued, “Persistent radiation induced xerostomia is a severe unmet need with a large, well defined patient population, strong physician enthusiasm, and a simple one-time in-office procedure. We believe AAV-hAQP1 has the potential to be clinically transformative and a very meaningful commercial opportunity.”

MeiraGTx’s conference call and webcast details are as follows:

- Thursday, April 16, 2026, at 8:00 a.m. ET.
- To register and attend the event, please click here

A live webcast of the event, as well as a replay, will be available on the Investors page of the Company’s website at www.investors.meiragtx.com/.

About the Phase 1 AQUAx Clinical Trial

The Phase 1 AQUAx clinical trial is an open-label, non-randomized, dose escalation trial designed to evaluate the safety of MeiraGTx's investigational gene therapy AAV-hAQP1 when administered via Stensen's duct to one or both parotid glands in patients who have been diagnosed with grade 2 or 3 radiation-induced xerostomia and who have remained cancer-free for at least five years (or at least two years if HPV+) after receiving radiation treatment for head and neck cancer. Primary endpoint of the trial is safety, with efficacy endpoints including patient-reported measures of xerostomia symptoms and the evaluation of the change in salivary output after treatment with AAV-hAQP1. Patients treated in the Phase 1 AQUAx study are followed for 5 years after the one-time administration of AAV-hAQP1.

About MeiraGTx

MeiraGTx (Nasdaq: MGTX) is a vertically integrated, clinical-stage genetic medicines company with a broad pipeline with four late-stage clinical programs. Each of these programs uses local delivery of small doses, resulting in disease-modifying effects in both inherited and more common diseases, in the eye, Parkinson's disease, and radiation-induced xerostomia. MeiraGTx uses its innovative technology in optimization of capsids, promoters, and novel translational control elements to develop best-in-class, potent, safe viral vectors. MeiraGTx's broad pipeline is supported by end-to-end in-house manufacturing. MeiraGTx has built the most comprehensive manufacturing capabilities in the industry, including two that are licensed for GMP viral vector production and a GMP QC facility with clinical and commercial licensure. In addition, MeiraGTx has developed a proprietary manufacturing platform process over 9 years based on more than 20 different viral vectors with leading yield and quality aspects and commercial readiness. Uniquely, MeiraGTx has developed a novel technology for in vivo delivery of any biologic therapeutic using oral small molecules. This transformative riboswitch gene regulation technology allows precise, dose-responsive control of gene expression by oral small molecules. MeiraGTx is focusing the riboswitch platform on the regulated in vivo delivery of metabolic peptides, including GLP-1, GIP, Glucagon, Amylin, PYY, and Leptin, as well as cell therapy, CAR-T for liquid and solid tumors and autoimmune diseases, and additionally, PNS targets addressing long-term intractable pain. MeiraGTx has developed the technology to apply genetic medicine to common diseases, increasing efficacy, addressing novel targets, and expanding access in some of the largest disease areas where the unmet need remains high.

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 milestones regarding our pre-clinical and clinical data, reporting of such data and the timing of results of data and regulatory matters, as well as statements that include the words "expect," "will," "intend," "plan," "believe," "project," "forecast," "estimate," "may," "could," "should," "would," "continue," "anticipate," "eligible" 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 or rare pediatric disease designations, retain key personnel or attract qualified employees, or incur expected levels of operating expenses; the impact of pandemics, epidemics or outbreaks of infectious diseases 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 Annual Report on Form 10-K for the year ended December 31, 2025, 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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