
**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 02, 2026

Ultragenyx Pharmaceutical Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-36276
(Commission File Number)

27-2546083
(IRS Employer
Identification No.)

**60 Leveroni Court
Novato, California**
(Address of Principal Executive Offices)

94949
(Zip Code)

Registrant's Telephone Number, Including Area Code: 415 483-8800

(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
Common Stock, \$0.001 par value	RARE	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 April 2, 2026, Ultragenyx Pharmaceutical Inc. (the “Company”) issued a press release announcing that the U.S. Food and Drug Administration (the “FDA”) has accepted for review the Company’s resubmitted Biologics License Application seeking accelerated approval for UX111 (rebisufligene etisparvovec) AAV9 gene therapy as a treatment for patients with Sanfilippo syndrome Type A (MPS IIIA). The FDA set a Prescription Drug User Fee Act (PDUFA) action date of September 19, 2026.

Cautionary Note Regarding 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. These statements may be identified by the use of words such as, but not limited to, “anticipates,” “expects,” “plans,” “continues,” “will,” “may,” “potential,” or other similar terms or expressions that concern the Company’s expectations, plans, objectives, and intentions.

Forward-looking statements include, without limitation, statements related to the Company’s expectations and projections, the development, regulatory status, review, timing and potential approval of UX111 (rebisufligene etisparvovec), including the anticipated PDUFA action date, the potential for accelerated approval, the outcome of the FDA’s review of the resubmitted Biologics License Application (BLA), the timing and outcome of any regulatory inspections, the sufficiency of clinical, biomarker and long-term follow-up data to support regulatory approval, expectations regarding the safety, tolerability and durability of UX111, manufacturing readiness and capabilities, including at third-party and company-owned manufacturing facilities, and the potential availability and commercial launch of UX111. Such forward-looking statements involve substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by the forward-looking statements. These risks and uncertainties include, among others, the uncertainty and unpredictability inherent in clinical drug development and the regulatory review and approval process; the possibility that the FDA may not accept or agree that the submitted data are sufficient to support accelerated or full approval of UX111; the risk that additional data, analyses or studies may be required; the timing, scope and outcome of regulatory inspections; risks related to the manufacture of UX111, including reliance on third-party manufacturers and the Company’s limited experience operating its own manufacturing facilities; the ability of the Company and its manufacturing partners to comply with regulatory requirements; potential safety or tolerability issues; competition from other therapies or products; smaller than anticipated market opportunities; and other risks related to the Company’s ability to fund operations, future operating results and financial performance.

The Company undertakes no obligation to update or revise any forward-looking statements. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to the business of the Company in general, see the Company’s Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC) on February 18, 2026, and its subsequent periodic reports filed with the SEC.

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.

Ultragenyx Pharmaceutical Inc.

Date: April 2, 2026

By: /s/ Howard Horn
Howard Horn
Executive Vice President, Chief Financial Officer, Corporate
Strategy
