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 19, 2026

Ultragenyx Pharmaceutical Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-36276**	**27-2546083**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
60 Leveroni Court Novato, California		**94949**
(Address of Principal Executive Offices)		**(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 August 19, 2026, Ultragenyx Pharmaceutical Inc. (“Ultragenyx” or the “Company”) announced the U.S. Food and Drug Administration (the “FDA”) granted accelerated approval for GENGLYCOS™ (pariglasgene brecaparvovec-opnr), also known as DTX401, in adult and pediatric patients eight years and older with glycogen storage disease type Ia (GSDIa).

Clinical Program and Post-Marketing Study Requirements Supporting Accelerated Approval of GENGLYCOS

The approval of GENGLYCOS is based on positive data from the 48-week randomized, double-blind, placebo-controlled Phase 3 GlucoGene study which treated 46 participants aged eight years and older with DTX401 (1.0 x 10^13 GC/kg dose) or placebo, showing a reduction in the cornstarch requirements in the treated group ($p<0.001$). There were 44 participants in the modified intention-to-treat (mITT) population providing efficacy data within the Week 48 analysis period following treatment with DTX401 (n=20) or placebo (n=24). At Week 48, eligible participants crossed over and received the alternate treatment. After crossover, participants continued to be followed, with analyses conducted at Week 96 and Week 144.

As part of accelerated approval, Ultragenyx has agreed to provide two years of safety and efficacy clinical data from open-label commercial treatment of 50 patients and 20 control patients through enhancement of its existing GSDIa Disease Monitoring Program (the “DMP”). The control group will consist of patients who sought commercial treatment but cannot be treated with GENGLYCOS due to the presence of anti-AAV8 antibodies. The study will provide more data to support the reduction in cornstarch clinical burden, fasting tolerance, and other measures in a post-marketing setting where patients can know their immediate glucose levels, and their cornstarch and diet can be managed more promptly by their physician. The DMP will also evaluate previously treated clinical trial participants as well as these new commercial patients for a total of 10 years.

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: August 19, 2026

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