

ULTRAGENYX PHARMACEUTICAL INC.

FORM 8-K (Current report filing)

Filed 12/18/17 for the Period Ending 12/14/17

Address	60 LEVERONI COURT NOVATO, CA, 94949
Telephone	415-483-8800
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Symbol	RARE
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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 14, 2017

ULTRAGENYX PHARMACEUTICAL INC.

(Exact name of registrant as specified in 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

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))

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

On December 14, 2017, Ultragenyx Pharmaceutical Inc. (the “*Company*”) and Ultragenyx International UX003 Ltd., a wholly-owned subsidiary of the Company (together with the Company, the “*Sellers*”), entered into an Asset Purchase Agreement (the “*Agreement*”) with Novartis Pharma AG pursuant to which the Sellers agreed to sell their Rare Pediatric Disease Priority Review Voucher (“*PRV*”). The PRV was awarded to the Company by the U.S. Food and Drug Administration in connection with the approval of Mepsevii™ (vestronidase alfa-vjbk). In consideration for the PRV, Novartis will pay the Sellers \$130,000,000 upon closing of the PRV purchase. Closing of the PRV purchase is subject to customary conditions, including the expiration or termination of the required waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976. The Agreement contains customary representations, warranties and covenants.

The foregoing summary of the Agreement is qualified in its entirety by the full text of the Agreement, a copy of which will be filed as an exhibit to the Company’s Annual Report on Form 10-K for the year ended December 31, 2017, and incorporated herein by reference.

On December 18, 2017, the Company also issued a press release announcing its entry into the Agreement. A copy of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference into this Item 1.01.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No. Description

99.1 Press Release, dated December 18, 2017

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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: December 18, 2017

Ultragenyx Pharmaceutical Inc.

By: /s/ Shalini Sharp

Name: Shalini Sharp

Title: Executive Vice President, Chief Financial
Officer



Contact Ultragenyx Pharmaceutical Inc.
Investors & Media
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Ultragenyx Sells Priority Review Voucher for \$130 million

Novato, CA, — December 18, 2017 — Ultragenyx Pharmaceutical Inc. (NASDAQ: RARE), a biopharmaceutical company focused on the development of novel products for rare and ultra-rare diseases, today announced that it has entered into a definitive agreement to sell its Rare Pediatric Disease Priority Review Voucher (PRV) to Novartis for \$130,000,000. Ultragenyx was awarded the voucher under a U.S. Food and Drug Administration (FDA) program intended to encourage the development of treatments for rare pediatric diseases. The Company received the PRV in November when MEPSEVII™ (vestronidase alfa) was approved by the U.S. FDA for the treatment of children and adults with Mucopolysaccharidosis VII (MPS VII, Sly syndrome).

“The sale of the PRV provides us with an important source of non-dilutive capital to help advance our pipeline of rare and ultra-rare therapies, and accelerates the availability of these potential therapies to patients,” said Emil D. Kakkis, M.D., Ph.D., Chief Executive Officer and President of Ultragenyx.

Under the agreement, Ultragenyx will receive a lump sum payment of \$130 million upon the closing of the transaction, which is subject to customary closing conditions including antitrust review.

About the Rare Pediatric Disease Priority Review Voucher Program

This U.S. FDA program is intended to encourage development of new drug and biological products for prevention and treatment of certain rare pediatric diseases. Under this program, a sponsor who receives an approval for a drug or biologic for a "rare pediatric disease" may qualify for a PRV that can be redeemed to receive a priority review of a subsequent marketing application for a different product. The sponsor receives the PRV upon approval of the rare pediatric disease product application and it can be sold or transferred.

About Ultragenyx Pharmaceutical Inc.

Ultragenyx is a biopharmaceutical company committed to bringing to market novel products for the treatment of rare and ultra-rare diseases, with a focus on serious, debilitating genetic diseases. The Company has rapidly built and advanced a diverse portfolio of product candidates with the potential to address diseases for which the unmet medical need is high, the biology for treatment is clear, and for which there are no approved therapies.

The Company is led by a management team experienced in the development and commercialization of rare disease therapeutics. Ultragenyx's strategy is predicated upon time and cost-efficient drug development, with the goal of delivering safe and effective therapies to patients with the utmost urgency.



For more information on Ultragenyx, please visit the Company's website at www.ultragenyx.com.

Forward Looking Statements

Except for the historical information contained herein, the matters set forth in this press release, including statements relating to Ultragenyx's expectations regarding the consummation of the transaction and the potential benefits of the transaction, are forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements involve substantial risks and uncertainties that could cause our clinical development programs, future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the uncertainties inherent in the clinical drug development process, such as the regulatory approval process, the timing of regulatory filings, and other matters that could affect sufficiency of existing cash, cash equivalents and short-term investments to fund operations and the availability or commercial potential of our drug candidates. Ultragenyx 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 Ultragenyx in general, see Ultragenyx's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 3, 2017, and its subsequent periodic reports filed with the Securities and Exchange Commission.