

**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): March 31, 2020

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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, \$0.001 par value	RARE	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 3.02 Unregistered Sale of Equity Securities

In connection with the strategic partnership and non-exclusive license and technology access agreement between Ultragenyx Pharmaceutical Inc. (the “Company”) and Daiichi Sankyo Company, Limited (“Daiichi Sankyo”) for the Company’s proprietary AAV-based gene therapy manufacturing technologies (the “License and Technology Access Agreement”) entered into on March 31, 2020, the Company sold an aggregate of 1,243,913 shares of common stock, par value \$0.001 per share of the Company (the “Shares”) to Daiichi Sankyo for an aggregate purchase price of \$75 million pursuant to the terms of a Stock Purchase Agreement dated as of March 31, 2020 (the “Stock Purchase Agreement”). Pursuant to the Stock Purchase Agreement, Daiichi Sankyo agreed to certain standstill provisions and restrictions on sale of the Shares. The sale restrictions will expire on March 31, 2023, which is also the earliest date when the standstill provisions will expire. Information regarding the License and Technology Access Agreement is set forth below in Item 8.01 of this Current Report on Form 8-K.

The issuance and sale of the Shares have not been registered under the Securities Act of 1933, as amended (the “Securities Act”). The Shares have been sold and issued in reliance on an exemption from the registration requirements of the Securities Act afforded by Section 4(a)(2) thereof.

Item 8.01 Other Events

On March 31, 2020, the Company issued a press release (the “Press Release”) announcing the License and Technology Access Agreement and the sale of shares to Daiichi Sankyo pursuant to the Stock Purchase Agreement. A copy of the Press Release is filed herewith as Exhibit 99.1 and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated March 31, 2020.
104	The cover page from the Company’s Current Report on Form 8-K dated March 31, 2020 formatted in Inline XBRL.

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.

Date: April 1, 2020

Ultragenyx Pharmaceutical Inc.

By: /s/ Shalini Sharp

Shalini Sharp

Executive Vice President, Chief Financial Officer



Ultragenyx Enters into Strategic Partnership with Daiichi Sankyo for Gene Therapy Manufacturing Technology

Daiichi Sankyo granted non-exclusive license to Ultragenyx HeLa manufacturing platform

Ultragenyx to receive \$200 million upfront, including \$125 million in cash and \$75 million via equity investment

Novato, Calif. — March 31, 2020 — Ultragenyx Pharmaceutical Inc. (NASDAQ: RARE), a biopharmaceutical company focused on the development and commercialization of novel products for serious rare and ultra-rare diseases, today announced a strategic partnership and non-exclusive license and technology access agreement with Daiichi Sankyo Company, Limited for Ultragenyx’s proprietary AAV-based gene therapy manufacturing technologies. Ultragenyx’s HeLa producer cell line (PCL) platform enables large commercial-scale AAV-based gene therapy product manufacturing that is intended to be highly reproducible, more consistent, and less expensive than other gene therapy manufacturing platforms. In addition, Ultragenyx has developed a proprietary HEK293 transient transfection system for AAV manufacture which is also a subject of the collaboration.

Under the license and technology access agreement, Ultragenyx granted Daiichi Sankyo a non-exclusive license to intellectual property, including know-how and patent applications, with respect to its HeLa PCL and HEK293 transient transfection manufacturing technology platforms for AAV-based gene therapy products. The parties will collaborate closely as part of a technology transfer plan to enable Daiichi Sankyo to use the technologies for its internal gene therapy programs. Ultragenyx retains the exclusive right to use its manufacturing technology for its current target indications and additional indications identified now and in the future.

“This new partnership with Daiichi Sankyo provides further validation of the value of Ultragenyx’s gene therapy-related technologies, especially our HeLa producer cell line platform that we believe is the most scalable mammalian cell AAV manufacturing system,” said Emil D. Kakkis, MD, PhD, Chief Executive Officer and President of Ultragenyx. “We are encouraged that our proprietary technologies continue to enable the development of numerous programs, both internally and for our partners, to treat patients with serious unmet medical needs.”

“We are currently doing discovery research for gene therapy drugs using AAV vectors as one of our focused modalities toward sustained growth beyond achievement of our 2025 vision,” said Masayuki Yabuta, PhD, Executive Officer, Head of Biologics Division, Daiichi Sankyo. “In order to provide these drugs to patients in the future, manufacturing technology must be established

early. Ultragenyx's proprietary technology is particularly excellent in terms of stable quality, high production efficiency, and ability to accommodate mass production.”

Daiichi Sankyo will be responsible for the manufacture, development, and commercialization of products manufactured with the Ultragenyx technology, except that Ultragenyx receives an option to co-develop and co-commercialize rare disease products at the IND stage. Ultragenyx will also provide strategic consultation to Daiichi Sankyo on the development of both AAV-based gene therapy products and other products for rare diseases.

Under the terms of the agreements, Daiichi Sankyo will make an upfront payment of \$125 million and will purchase \$75 million of Ultragenyx common stock at a price of approximately \$60 per share. Daiichi Sankyo will pay an additional \$25 million upon completion of the technology transfer of the HeLa PCL and HEK293 platforms as well as single-digit royalties on net sales of products manufactured in either system. Daiichi Sankyo will reimburse Ultragenyx for all costs associated with the transfer of the manufacturing technology.

About Ultragenyx Pharmaceutical Inc.

Ultragenyx is a biopharmaceutical company committed to bringing patients novel products for the treatment of serious rare and ultra-rare genetic diseases. The company has built a diverse portfolio of approved therapies and product candidates aimed at addressing diseases with high unmet medical need and clear biology for treatment, for which there are typically no approved therapies treating the underlying disease.

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.

About Daiichi Sankyo

Daiichi Sankyo Group is dedicated to the creation and supply of innovative pharmaceutical therapies to improve standards of care and address diversified, unmet medical needs of people globally by leveraging our world-class science and technology. With more than 100 years of scientific expertise and a presence in more than 20 countries, Daiichi Sankyo and its 15,000 employees around the world draw upon a rich legacy of innovation and a robust pipeline of promising new medicines to help people. In addition to a strong portfolio of medicines for cardiovascular diseases, under the Group’s 2025 Vision to become a “Global Pharma Innovator

with Competitive Advantage in Oncology,” Daiichi Sankyo is primarily focused on providing novel therapies in oncology, as well as other research areas centered around rare diseases and immune disorders. For more information, please visit: www.daiichisankyo.com.

Forward-Looking Statements

Except for the historical information contained herein, the matters set forth in this press release, including statements related to Ultragenyx's expectations regarding plans for its clinical programs and clinical studies, future regulatory interactions, and the components and timing of regulatory submissions 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, collaboration with third parties, 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 approvals (including whether such approvals can be obtained), 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 products and 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 Annual Report filed on Form 10-K with the Securities and Exchange Commission on February 14, 2020, and its subsequent periodic reports filed with the Securities and Exchange Commission.

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Investors & Media

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