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): February 25, 2016

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)	(I.R.S. 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

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))

Item 2.02. Results of Operations and Financial Condition.

On February 25, 2016, Ultragenyx Pharmaceutical Inc. issued a press release announcing its financial results for the three months ended December 31, 2015 and the year ended December 31, 2015 (the "***Press Release***"). A copy of the Press Release is furnished herewith as Exhibit 99.1.

The information set forth under Item 2.02 and in Exhibit 99.1 shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, except as shall be expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated February 25, 2016

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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: February 25, 2016

Ultragenyx Pharmaceutical Inc.

By: /s/ Shalini Sharp
Shalini Sharp
Senior Vice President, Chief Financial Officer

Exhibit 99.1

Contact Ultragenyx Pharmaceutical Inc.
Investors & Media
Ryan Martins
844-758-7273

Ultragenyx Reports Fourth Quarter 2015 and Full-Year 2015 Financial Results and Corporate Update

NOVATO, CA – February 25, 2016 – Ultragenyx Pharmaceutical Inc. (NASDAQ: RARE), a biopharmaceutical company focused on the development of novel products for rare and ultra-rare diseases, today reported its financial results and corporate update for the fourth quarter and full-year ended December 31, 2015.

“2015 was a transformative year for Ultragenyx in which we advanced our entire product portfolio providing new possibilities for the treatment of rare disease patients,” said Emil D. Kakkis, M.D., Ph.D., Chief Executive Officer and President of Ultragenyx. “In 2016, we expect to have many clinical, regulatory and business development updates as we potentially begin transitioning from a clinical development stage to a commercial company.”

Fourth Quarter and Full-Year 2015 Financial Results

For the fourth quarter of 2015, Ultragenyx reported a net loss attributable to common stockholders of $55.2 million, or $1.42 per share, basic and diluted, compared with a net loss attributable to common stockholders for the fourth quarter of 2014 of $16.7 million, or $0.52 per share, basic and diluted. This reflected cash used in operations of $40.4 million in the fourth quarter of 2015 compared to $12.5 million in the fourth quarter of 2014. For the year ended December 31, 2015, net loss attributable to common stockholders was $145.6 million, or $3.96 per share, basic and diluted, compared with a net loss attributable to common stockholders for the same period in 2014 of $64.6 million, or $2.25 per share, basic and diluted. This reflected cash used in operations of $106.0 million in the year ended December 31, 2015 compared to $44.6 million in the same period of 2014. Net loss attributable to common stockholders differs from net loss due to dividends and other charges related to outstanding preferred stock, which was converted into common stock upon the company’s initial public offering.

Total operating expenses for the fourth quarter of 2015 were $56.2 million compared with $16.9 million for the same period in 2014. This included a one-time upfront payment to Arcturus of $10 million in the fourth quarter of 2015. Non-cash stock-based compensation accounted for $9.5 million and $2.0 million of total operating expenses in the fourth quarter of 2015 and 2014, respectively. Total operating expenses for the year ended December 31, 2015 were $147.7 million compared with $56.8 million for the same period in 2014. Non-cash stock-based compensation accounted for $24.9 million and $5.4 million of total operating expenses in 2015 and 2014, respectively. The increase in total operating expenses is due to

the increase in development, commercial, and general and administrative costs as the company grows and advances its pipeline, including related increases in stock compensation expenses.

Cash, cash equivalents, and investments were $536.3 million as of December 31, 2015.

Recent Highlights & Upcoming Milestones

KRN23 anti-FGF23 Monoclonal Antibody in X-Linked Hypophosphatemia (XLH) and Tumor-Induced Osteomalacia (TIO)

- **40-week data in 52 pediatric XLH patients are expected in the second half of 2016.** Safety and efficacy data, including rickets scores (RSS and RGI-C) from 52 patients at 40 weeks in the pediatric Phase 2 study are expected. In addition, 64 week data from a subset of patients is also expected at this time, including data on height growth velocity. Ultragenyx and Kyowa Hakko Kirin plan to file for conditional marketing authorization approval around the end of 2016 based on these data.
- **Phase 3 study in pediatric XLH patients expected to initiate in mid-2016.** The study will likely utilize RGI-C as the primary endpoint and would include a standard of care reference arm. This study is expected to be required for potential approval in the US and could also serve as a confirmatory study in the EU if a conditional marketing authorization were granted.
- **Phase 3 study in adult XLH patients initiated in December 2015.** The Phase 3 study is an international randomized, double-blind, placebo-controlled clinical study that will assess the efficacy and safety of monthly KRN23 at 24 weeks in approximately 120 adult XLH patients. The primary endpoint of the study will be serum phosphorus levels through 24 weeks and the key secondary endpoint is the Brief Pain Inventory Question 3 (pain at its worst in the last 24 hours) at week 24. Other secondary endpoints include patient reported outcomes assessing skeletal pain, stiffness, fatigue, motor function, and quality of life in these patients. A 48-week open-label bone quality study in approximately ten adult XLH patients evaluating the potential impact of KRN23 on the underlying osteomalacia via bone biopsy is currently enrolling patients.
- **Interim Phase 2 study data in TIO is expected in the first half of 2016.** Interim data from the first patients enrolled in this six-patient open-label study are expected in the first half of 2016.

rhGUS in Mucopolysaccharidosis 7 (MPS 7)

- **Phase 3 study data are expected in mid-2016.** The pivotal blinded placebo-controlled 48-week study is fully enrolled, and data are expected in mid-2016. Outside of the US, the primary endpoint is the reduction in urinary glycosaminoglycans (GAG) excretion after 24 weeks of treatment. In the US, there is no primary endpoint declared; the Food and Drug Administration (FDA) will consider the totality of data on a per-patient basis.

- **Patients continue to be treated in the Phase 2 study of patients under five years of age and on an expanded access basis.** Multiple patients with MPS 7, including some with non-immune hydrops fetalis, a severe infantile presentation of the disease, continue to receive rhGUS treatment via these studies.

UX007 in Long-Chain Fatty Acid Oxidation Disorders (LC-FAOD) and Glut1 Deficiency Syndrome (Glut1 DS)

- **Data at 78 weeks from the Phase 2 study in LC-FAOD are expected in the second half of 2016.** Major medical event rate data comparing approximately 18 months before and after UX007 treatment are expected in the second half of 2016.
- **Phase 3 study in LC-FAOD patients expected to initiate in 2017.** Based on the interim 24-week results, Ultragenyx continues to plan for a Phase 3 study in LC-FAOD. The Phase 3 trial design and endpoints continue to be optimized prior to discussion with regulators. Further details are expected to be provided after discussions with regulatory authorities.
- **Phase 2 seizure study data in Glut1 DS patients are expected in the second half of 2016, pending enrollment.** The Phase 2 study in Glut1 DS patients with seizures continues to enroll patients. The study is evaluating generalized and partial tonic-clonic seizures by patient diary, absence seizures by EEG, and cognitive function.
- **Phase 3 movement disorder study in Glut1 DS patients is expected to initiate in the second half of 2016.** Following an End-of-Phase 2 meeting with the FDA, we are planning to initiate a Phase 3 clinical study in Glut1 DS patients with the movement disorder phenotype. The study is expected to enroll approximately 40 patients and is expected to be a randomized, double-blind, placebo-controlled, double cross-over study. The primary endpoint will be an assessment of the impact of UX007 on movement disorder events as recorded by a patient diary that is being further refined in discussions with the FDA.

Aceneuramic Acid Extended Release (Ace-ER) in GNE Myopathy

- **CHMP opinion on conditional marketing authorization application in Europe is expected in the second half of 2016.** The company is seeking conditional approval from the European Medicines Agency (EMA) for Ace-ER in the treatment of adults with GNE myopathy based on positive data from the Phase 2 randomized, double-blind, placebo-controlled study. In October 2015 we announced the filing and acceptance of an MAA seeking conditional approval from the EMA for the use of six grams per day of Ace-ER tablets in the treatment of GNE myopathy.

- **Enrollment in pivotal Phase 3 study in GNE Myopathy ongoing.** The randomized, double-blind, placebo-controlled international 48-week study in approximately 80 patients was initiated in May 2015. The study is evaluating the efficacy of Ace-ER with the primary endpoint of a composite of upper extremity muscle strength. Data from the study are expected in 2017.

Conference Call & Webcast Information

Ultragenyx will host a conference call today, Thursday, February 25, 2016 at 5pm ET to discuss fourth quarter and full-year 2015 financial results and to provide a corporate update. The live and replayed webcast of the call will be available through the company's website at http://ir.ultragenyx.com/events.cfm. To participate in the live call by phone, dial 855-797-6910 (USA) or 262-912-6260 (international) and enter the passcode 45371417. The replay of the call will be available for one year.

About Ultragenyx

Ultragenyx is a clinical-stage 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. Founded in 2010, the company has rapidly built 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 regarding Ultragenyx's expectations regarding the timing of release of additional data for its product candidates, plans to initiate additional studies for its product candidates and timing regarding these studies, plans regarding ongoing studies for existing programs and its intent to file for conditional approval, 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 (including with respect to the MAA we filed seeking conditional approval from EMA with respect to Ace-ER), the timing of our 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 the company in general, see Ultragenyx's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 10, 2015, and its subsequent periodic reports filed with the Securities and Exchange Commission.

Ultragenyx Pharmaceutical Inc.
Selected Statements of Operations Financial Data
(in thousands, except share and per share amounts)

	(unaudited) Three Months Ended December 31,		Year Ended December 31,	
	2015	2014	2015	2014
Statements of Operations Data:				
Operating expenses:				
Research and development	$ 44,565	$ 13,521	$ 114,737	$ 45,967
General and administrative	11,593	3,422	33,001	10,811
Total operating expenses	56,158	16,943	147,738	56,778
Loss from operations	(56,158)	(16,943)	(147,738)	(56,778)
Other income (expense), net	938	205	2,120	(3,024)
Net loss	$ (55,220)	$ (16,738)	$ (145,618)	$ (59,802)
Net loss attributable to common stockholders	$ (55,220)	$ (16,738)	$ (145,618)	$ (64,610)
Net loss per share attributable to common stockholders, basic and diluted	$ (1.42)	$ (0.52)	$ (3.96)	$ (2.25)
Shares used to compute net loss per share attributable to common stockholders, basic and diluted	38,847,922	31,897,138	36,782,603	28,755,758

Ultragenyx Pharmaceutical Inc.
Selected Balance Sheets Financial Data
(in thousands)
(unaudited)

	December 31, 2015	December 31, 2014
Balance Sheet Data:		
Cash, cash equivalents and investments	$ 536,256	$ 187,487
Working capital	422,289	180,899
Total assets	559,569	197,967
Total stockholders' equity	531,090	184,945