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): November 9, 2015

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 November 9, 2015, Ultragenyx Pharmaceutical Inc. issued a press release announcing its financial results for the nine months ended September 30, 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 November 9, 2015.

* * *

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: November 9, 2015

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 Third Quarter 2015 Financial Results and Corporate Update

NOVATO, CA – November 9, 2015 – 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 quarter ended September 30, 2015.

“We have continued to make progress across our product portfolio, including filing for conditional approval in Europe with Ace-ER, reporting interim data for UX007 in long chain fatty acid oxidation disorders (LC-FAOD) and in five infants with cardiomyopathy due to LC-FAOD, announcing plans to initiate a Phase 3 study with UX007 in Glut1 DS patients with the movement disorder phenotype, and initiating a multi-target collaboration for messenger RNA (mRNA) therapeutics,” said Emil D. Kakkis, M.D., Ph.D., Chief Executive Officer and President of Ultragenyx. “We look forward to closing out the year with the 36-patient data from the Phase 2 study of KRN23 in pediatric XLH patients and Ultragenyx’s first R&D day in New York on December 3.”

Third Quarter 2015 Financial Results

For the third quarter of 2015, Ultragenyx reported a net loss attributable to common stockholders of $39.2 million, or $1.03 per share, basic and diluted, compared with a net loss attributable to common stockholders for the third quarter of 2014 of $15.8 million, or $0.50 per share, basic and diluted. For the nine months ended September 30, 2015, net loss attributable to common stockholders was $90.4 million, or $2.51 per share, basic and diluted, compared with a net loss attributable to common stockholders for the same period in 2014 of $47.9 million, or $1.73 per share, basic and diluted. 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 third quarter of 2015 were $39.9 million compared with $15.8 million for the same period in 2014. Non-cash stock-based compensation accounted for $7.9 million and $1.7 million of total operating expenses in the third quarter of 2015 and 2014, respectively. Total operating expenses for the nine months ended September 30, 2015 were $91.6 million compared with $39.8 million for the same period in 2014. Non-cash stock-based compensation accounted for $15.4 million and $3.4 million of total operating expenses in the first nine months of 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, as well as related increases in stock compensation expenses.

Cash, cash equivalents, and investments were $581.9 million as of September 30, 2015.

Recent Highlights & Upcoming Milestones

Corporate Updates

- **Research collaboration and license agreement initiated for messenger RNA (mRNA) therapeutics**. Ultragenyx entered into an agreement with Arcturus Therapeutics, Inc. to develop mRNA therapeutics for two selected rare disease targets, with the option to expand to eight additional targets. The collaboration is intended to address a wider range of rare diseases than is possible with currently available enzyme replacement therapy approaches.
- **Research & Development Day to be held on December 3, 2015**. The company will hold its first Research & Development Day for analysts and investors on Thursday, December 3, 2015 at 12:30 p.m. ET in New York, NY. An update on the company's pipeline will be provided.

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

- **Phase 2 40-week data in 36 pediatric XLH patients expected by the end of 2015**. Safety and efficacy data, including rickets scores, from 36 patients in the pediatric Phase 2 study are expected by year-end. The study has been expanded to enroll a total of 52 patients, and 40-week results for the fully expanded study are expected in mid-2016. Based on the results of the 36-patient data, the company will make a determination on filing for conditional approval in Europe based on prior scientific advice received.
- **Phase 3 program in adult XLH patients expected to initiate by year-end 2015**. Ultragenyx continues initiation activities for the Phase 3 randomized, double-blind, placebo-controlled study in approximately 120 adult XLH patients. The primary endpoint will be serum phosphorus levels at 24 weeks, with the Brief Pain Inventory (BPI) patient-reported outcome as a key secondary endpoint. The company also plans to initiate a 48-week open-label bone biopsy study in approximately ten patients to evaluate the effect of KRN23 on osteomalacia.
- **Phase 2 study enrollment of the planned 6 patients in TIO is completed**. Interim data from the first few patients are expected in early 2016.

rhGUS in Mucopolysaccharidosis 7 (MPS 7)

- **Phase 3 study in MPS 7 ongoing**. The pivotal blinded placebo-controlled 48-week study is fully enrolled and data are expected in mid-2016. The primary endpoint is the reduction in urinary glycosaminoglycans (GAG) excretion after 24 weeks of treatment for outside the US. There is no primary endpoint for the US where the FDA will consider the totality of data on a per patient basis.
- **Patients continue to be treated in the Phase 2 study, the under 5 years old study, 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. Interim data are expected by the end of 2016.

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

- **Positive 24-week interim results from Phase 2 study in LC-FAOD**. Data from the open-label study suggest improvements in key measures of exercise tolerance (cycle ergometry and 12-minute walk test) in patients with musculoskeletal symptoms who were able to complete the tests. Overall major medical events (hypoglycemia, rhabdomyolysis, and cardiomyopathy) appeared to decrease in the patients who completed the 24 weeks of treatment compared to the rate reported prior to treatment with UX007 but this will need more time to verify a clear difference. These data will be evaluated again at the 78-week time point and are expected in the second half of 2016.

  Four of the 29 patients discontinued prior to 24 weeks, including only one for diarrhea attributed to UX007. The three other patients withdrew consent for reasons unrelated to UX007 treatment. All the remaining 25 patients opted to stay on drug after 24 weeks. One serious related adverse event for moderate gastroenteritis with vomiting was considered treatment-related. Overall, 18 patients (62%) had treatment-related adverse events, most of which were mild-to-moderate in nature. The most common treatment-related adverse events were diarrhea, abdominal/gastrointestinal pain, and vomiting.
- **Interim Phase 2 data in LC-FAOD support advancement to Phase 3**. Based on the interim results, the company intends to begin planning for a Phase 3 study in LC-FAOD and further details are expected to be provided after discussions with regulatory authorities in the first half of 2016.
- **Data from compassionate use of UX007 in infants with cardiomyopathy due to LC-FAOD presented at SSIEM**. Case reports from five patients were reported at the Society for the Study of Inborn Errors of Metabolism (SSIEM). While on the standard of care, medium-chain triglyceride (MCT) oil, patients were hospitalized with heart failure that required cardiac support and, in some cases, resuscitation. The patients discontinued MCT oil and then began to receive UX007. All patients demonstrated an improvement in ejection fraction (EF), a measure of cardiac function evaluated by echocardiogram, after treatment

with UX007. The most common adverse events were gastrointestinal distress, including loose stools. One patient discontinued treatment after approximately 14 weeks due to gastrointestinal symptoms.

- **Development program for UX007 in multiple manifestations (seizures and movement disorders) of Glut1 DS**. 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. 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 in mid-2016. If positive, the two studies are intended to support an NDA filing for the treatment of Glut1 DS. The company will no longer be conducting an interim analysis of the current Phase 2 study in the seizure phenotype to preserve the integrity of the Phase 2 study and maximize its utility from a regulatory perspective.

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

- **MAA filed and accepted for review by European Medicines Agency (EMA)**. The company is seeking conditional approval from the 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. We recently 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. A decision from the European Commission would be expected in the second half of 2016.
- **Enrollment in pivotal Phase 3 study in GNE Myopathy ongoing**. The randomized, double-blind, placebo-controlled 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 the first half of 2017.

Conference Call & Webcast Information

Ultragenyx will host a conference call today, Monday, November 9, 2015 at 5pm ET to discuss third quarter 2015 financial results and 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 71521135. 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 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, including the regulatory approval process, 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 August 14, 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 September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Statements of Operations Data:				
Operating expenses:				
Research and development	$ 29,704	$ 12,854	$ 70,172	$ 32,446
General and administrative	10,232	2,981	21,408	7,389
Total operating expenses	39,936	15,835	91,580	39,835
Loss from operations	(39,936)	(15,835)	(91,580)	(39,835)
Other income (expense), net	704	(14)	1,182	(3,229)
Net loss	$ (39,232)	$ (15,849)	$ (90,398)	$ (43,064)
Net loss attributable to common stockholders	$ (39,232)	$ (15,849)	$ (90,398)	$ (47,872)
Net loss per share attributable to common stockholders, basic and diluted	$ (1.03)	$ (0.50)	$ (2.51)	$ (1.73)
Shares used to compute net loss per share attributable to common stockholders, basic and diluted	38,268,632	31,631,385	36,086,598	27,697,137

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

	September 30, 2015	December 31, 2014
Balance Sheet Data:		
Cash, cash equivalents and investments	$ 581,875	$ 187,487
Working capital	435,974	180,899
Total assets	602,130	197,967
Total stockholders' equity	576,763	184,945