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): August 8, 2016

ULTRAGENYX PHARMACEUTICAL INC.
(Exact Name of Registrant as Specified in 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

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 August 8, 2016, Ultragenyx Pharmaceutical Inc. issued a press release announcing its financial results for the three and six months ended June 30, 2016 (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 August 8, 2016

*** * ***

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: August 8, 2016

ULTRAGENYX PHARMACEUTICAL INC.

By: /s/ Shalini Sharp
Name: Shalini Sharp
Title: Executive Vice President, Chief Financial Officer

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release, dated August 8, 2016

Exhibit 99.1

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

Ultragenyx Reports Second Quarter 2016 Financial Results and Corporate Update

NOVATO, CA – August 8, 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 quarter ended June 30, 2016.

“We are advancing and building our pipeline, with recent positive data from our Phase 3 study of rhGUS in MPS 7, completion of enrollment in two Phase 3 programs including KRN23 in adult X-linked hypophosphatemia and Ace-ER in GNE myopathy, and entry into a broad partnership with Takeda that provides a source of new product candidates to treat rare genetic diseases,” said Emil D. Kakkis, M.D., Ph.D., Chief Executive Officer and President of Ultragenyx. “We expect continued clinical and regulatory progress, with key milestones across each of our programs anticipated in the next twelve months.”

Second Quarter 2016 Financial Results

For the second quarter of 2016, Ultragenyx reported a net loss of $56.9 million, or $1.46 per share, basic and diluted, compared with a net loss for the second quarter of 2015 of $29.8 million, or $0.83 per share, basic and diluted. For the six months ended June 30, 2016, net loss was $109.7 million, or $2.81 per share, basic and diluted, compared with a net loss for the same period in 2015 of $51.2 million, or $1.46 per share, basic and diluted. This reflected cash used in operations of $84.6 million for the six months ended June 30, 2016 compared to $34.9 million for the same period in 2015.

Total operating expenses for the second quarter of 2016 were $58.1 million compared with $30.1 million for the same period in 2015, including non-cash stock-based compensation of $10.9 million and $5.1 million in the second quarter of 2016 and 2015, respectively. Total operating expenses for the six months ended June 30, 2016 were $111.7 million compared with $51.6 million for the same period in 2015, including non-cash stock-based compensation of $21.1 million and $7.5 million in the first half of 2016 and 2015, 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.

Cash, cash equivalents, and investments were $441.8 million as of June 30, 2016.

Recent Highlights

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

- **Breakthrough Therapy Designation for pediatric patients with XLH.** In June, the U.S. Food and Drug Administration (FDA) granted breakthrough therapy designation to KRN23 for the treatment of X-linked hypophosphatemia (XLH) in pediatric patients one year of age and older.
- **Enrollment complete in Phase 3 study in adult XLH patients; data expected in the first half of 2017.** The Phase 3 study will evaluate change in serum phosphorus levels, pain, stiffness, physical function, and safety of monthly KRN23 compared with placebo over 24 weeks in 134 adult XLH patients.

rhGUS in Mucopolysaccharidosis 7 (MPS 7)

- **Positive Topline Data from Phase 3 pivotal study.** The study met its primary endpoint of reducing urinary GAG excretion after 24 weeks of treatment, demonstrating a reduction from baseline of 64.8 percent ($p<0.0001$). The Multi-domain Responder Index (MDRI) provided evidence of clinical improvement with rhGUS treatment. The MDRI score at 24 weeks of treatment, a secondary endpoint, demonstrated an overall mean improvement (±SD) of +0.5 domains (±0.80) ($p=0.0527$). Treatment-emergent adverse events were generally mild to moderate in severity. There were two serious adverse events including a Grade 3 treatment related anaphylactoid event and a Grade 2 unrelated event from an accidental injury.

Ace-ER in GNE Myopathy

- **Enrollment complete in pivotal Phase 3 study in GNE myopathy; data expected in 2017.** The randomized, double-blind, placebo-controlled international study in 89 patients is evaluating the efficacy and safety of Ace-ER compared with placebo over 48 weeks.

Corporate Updates

- **Strategic collaboration established with Takeda Pharmaceutical Company Limited to develop and commercialize therapies to treat rare genetic diseases.** Ultragenyx entered into a collaboration with Takeda and will receive an exclusive license to one preclinical Takeda product candidate in a pre-determined field of use, an exclusive option to co-develop and co-commercialize the product candidate in additional therapeutic areas, and an option to license up to five additional Takeda product candidates for rare diseases through a five-year research collaboration. In July, the deal closed and Takeda purchased 374,590 shares for $40 million, or an effective price of $106.78 per share.
- **General Counsel appointed.** In June 2016, Ultragenyx appointed Karah Parschauer as Executive Vice President, General Counsel.

Upcoming Milestones

KRN23 in XLH and TIO

- **Phase 3 study in pediatric XLH patients expected to initiate in mid-2016.** The study will utilize the RGI-C rickets score as the primary endpoint and will include a reference arm of oral phosphate and Vitamin D.
- **40-week data in 52 patients and 64-week data in 36 patients in the Phase 2 pediatric XLH study expected in the second half of 2016.** Safety and efficacy data, including rickets scores (RSS and RGI-C) from 52 patients at 40 weeks, and height growth velocity from 36 patients at 64 weeks, will be available.
- **Ultragenyx and Kyowa Hakko Kirin plan to file for conditional marketing authorization in the European Union for the treatment of XLH around the end of 2016.**
- **Interim bone data from Phase 2 study in TIO expected second half 2016.** The open-label, dose-finding Phase 2 study is evaluating the safety and efficacy of KRN23 in approximately fifteen adult patients. Full 24-week bone data on the first eight patients will be available in the second half of 2016.

rhGUS in MPS 7

- **Ultragenyx plans to meet with FDA and EMA in the second half of 2016 to discuss plans to submit regulatory filings in the first half of 2017, based on Phase 3 study results.** In Europe, the primary endpoint is the percent reduction in urinary glycosaminoglycans (GAG) excretion after 24 weeks of treatment. The EMA has indicated that some evidence or trend in improvement in clinical endpoints would also be necessary for approval. In the US, there is no primary endpoint declared; the FDA will consider the totality of data on a per-patient basis.

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 expected in the second half of 2016.** Data will include a comparison of major medical event rates approximately 18 months before and after UX007 treatment. Long-term safety and exercise tolerance data will also be provided.
- **Phase 2 seizure study data in Glut1 DS patients expected in the second half of 2016.** The ongoing placebo-controlled study is evaluating frequency of 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 expected to initiate in the second half of 2016.** The study is expected to enroll approximately 40 patients and be a randomized, double-blind, placebo-controlled, double cross-over study. The study is designed to assess the impact of UX007 on movement disorder events as recorded by a patient diary. The company is working on further substantiating the clinical meaningfulness of Glut1 DS movement disorder events prior to finalizing the study design.

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

- **CHMP opinion on conditional marketing authorization application in Europe expected in the second half of 2016, and a decision is expected in the first half of 2017.** The company is seeking conditional marketing authorization 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.

Conference Call & Webcast Information

Ultragenyx will host a conference call today, Monday, August 8, 2016 at 5pm ET to discuss second quarter 2016 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 55432770. 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.

Ultragenyx has completed a Phase 3 study of recombinant human beta-glucuronidase (rhGUS) in patients with mucopolysaccharidosis 7 (MPS 7), a rare lysosomal storage disease, and is currently conducting a Phase 3 study of aceneuramic acid extended-release (Ace-ER) in patients with GNE myopathy, a progressive muscle-wasting disorder; a Phase 2 clinical study for UX007 in patients with glucose transporter type-1 deficiency syndrome (Glut1 DS), a brain energy deficiency; a Phase 2 clinical study of UX007 in patients severely affected by long-chain fatty acid oxidation disorders (LC-FAOD), a genetic disorder in which the body is unable to convert long chain fatty acids into energy; and Phase 2 and Phase 3 studies of KRN23, an antibody targeting fibroblast growth factor 23 (FGF23), in patients with X-linked hypophosphatemia (XLH) and tumor induced osteomalacia (TIO), both rare diseases that impair bone mineralization.

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, its intent to file for conditional approval and its expectations regarding timing of receiving potential approval of its product candidates, 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), whether the Phase 3 results for Ace-ER will in fact confirm or mirror the results from the prior Phase 2 study, and whether the FDA and/or EMA will accept the primary endpoint from the Phase 3 study of 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 May 10, 2016, 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 June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Statements of Operations Data:				
Revenue	$ 17	$ —	$ 17	$ —
Operating expenses:				
Research and development	43,332	23,104	83,747	40,468
General and administrative	14,738	7,038	27,945	11,176
Total operating expenses	58,070	30,142	111,692	51,644
Loss from operations	(58,053)	(30,142)	(111,675)	(51,644)
Other income, net	1,130	355	1,995	478
Net loss	$ (56,923)	$ (29,787)	$ (109,680)	$ (51,166)
Net loss per share, basic and diluted	$ (1.46)	$ (0.83)	$ (2.81)	$ (1.46)
Shares used in computing net loss per share, basic and diluted	39,028,701	35,937,442	38,999,439	34,997,498

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

	June 30, 2016	December 31, 2015
Balance Sheet Data:		
Cash, cash equivalents and investments	$ 441,824	$ 536,256
Working capital	379,101	422,289
Total assets	481,951	559,569
Total stockholders' equity	443,895	531,090