Ultragenyx Pharmaceutical Inc. Form 10-Q November 08, 2016
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549
FORM 10-Q
(Mark One)
QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934. For the quarterly period ended September 30, 2016
OR
TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.  For the transition period from to .
Commission File No. 001-36276
ULTRAGENYX PHARMACEUTICAL INC.
(Exact name of registrant as specified in its charter)
Delaware 27-2546083 (State or other jurisdiction of incorporation or organization) Identification No.)

(Address of principal executive offices) (Zip Code)

94949

60 Leveroni Court Novato, California

(415) 483-8800

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities and Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

YES NO

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). YES NO

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer (Do not check if a smaller reporting company) Smaller reporting company Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES NO

As of November 3, 2016, the registrant had 40,859,861 shares of common stock issued and outstanding.

## ULTRAGENYX PHARMACEUTICAL INC.

# FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2016

INDEX

			Page		
CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS					
Part I – <u>Financial Information</u>					
	Item 1.	Condensed Consolidated Financial Statements – Unaudited			
		Condensed Consolidated Balance Sheets	2		
		Condensed Consolidated Statements of Operations	3		
		Condensed Consolidated Statements of Comprehensive Loss	4		
		Condensed Consolidated Statements of Cash Flows	5		
		Notes to Condensed Consolidated Financial Statements	6		
	Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	12		
	Item 3.	Quantitative and Qualitative Disclosures About Market Risk	26		
	Item 4.	Controls and Procedures	26		
Part II – Other Information					
	Item 1.	Legal Proceedings	27		
	Item 1A.	Risk Factors	27		
	Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	57		
	Item 3.	Defaults Upon Senior Securities	57		
	Item 4.	Mine Safety Disclosures	57		
	Item 5.	Other Information	58		
	Item 6.	<u>Exhibits</u>	58		
	Signatures		59		

#### CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements that involve risks and uncertainties. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q are forward-looking statements. In some cases, you can identify forward-looking statements by words such as "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "seek," "should," "target," "will," "would," or the negative of these comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- our expectations regarding the timing of clinical study commencements and reporting results from same;
- the timing and likelihood of regulatory approvals for our product candidates;
- the potential market opportunities for commercializing our product candidates;
- our expectations regarding the potential market size and the size of the patient populations for our product candidates, if approved for commercial use;
- estimates of our expenses, future revenue, capital requirements, and our needs for additional financing;
- our ability to develop, acquire, and advance product candidates into, and successfully complete, clinical studies;
- the implementation of our business model and strategic plans for our business and product candidates;
- the initiation, timing, progress, and results of future preclinical studies and clinical studies, and our research and development programs;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates;
- our ability to maintain and establish collaborations or obtain additional funding;
- our ability to maintain and establish relationships with third parties, such as contract research organizations, suppliers, and distributors;
- our financial performance and the expansion of our organization;
- our ability to obtain supply of our product candidates;
- developments and projections relating to our competitors and our industry; and
  - other risks and uncertainties, including those listed under Part II, Item 1A. Risk Factors.

Any forward-looking statements in this Quarterly Report on Form 10-Q reflect our current views with respect to future events or to our future financial performance and involve known and unknown risks, uncertainties, and other factors that may cause our actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those discussed under Part II, Item 1A. Risk Factors and discussed elsewhere in this Quarterly Report on Form 10-Q. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

This Quarterly Report on Form 10-Q also contains estimates, projections, and other information concerning our industry, our business, and the markets for certain diseases, including data regarding the estimated size of those markets, and the incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research, or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market, and other data from reports, research surveys, studies, and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data, and similar sources.

#### PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

#### ULTRAGENYX PHARMACEUTICAL INC.

#### CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited)

(In thousands, except share amounts)

	September 30, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	\$142,280	\$ 93,569
Short-term investments		343,428
Restricted cash	1,411	150
Prepaid expenses and other current assets	18,944	13,060

Date: November 14, 2002

#### CERTIFICATION

- I, Judy M. Robinett, certify that:
- 1. I have reviewed this quarterly report on Form 10-QSB of Medical Discoveries, Inc.;
- 2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;
- 4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and I have:
- a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to me by others within those entities, particularly during the period in which this quarterly report is being prepared;
- b) evaluated the effectiveness of the registrant s disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the Evaluation Date ); and
- c) presented in this quarterly report my conclusions about the effectiveness of the disclosure controls and procedures based on my evaluation as of the Evaluation Date;

- 5. I have disclosed, based on my most recent evaluation, to the registrant s auditors and the audit committee of registrant s board of directors (or persons performing the equivalent function):
- a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant s ability to record, process, summarize and report financial data and have identified for the registrant s auditors any material weaknesses in internal controls; and
- b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant s internal controls; and
- 6. I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: November 14, 2002

#### /S/ JUDY M. ROBINETT

Judy M. Robinett
Chief Executive Officer and principal financial officer
11