



60 Leveroni Court  
Novato, California 94949

May 17, 2024

**VIA EDGAR**

U.S. Securities and Exchange Commission  
Division of Corporation Finance  
100 F Street, N.E.  
Mail Stop 4720  
Washington, D.C. 20549  
Attn: Tracie Mariner; Kevin Vaughn

RE: **Ultragenyx Pharmaceutical Inc.**  
**Form 10-K for Fiscal Year Ended December 31, 2023**  
**File No. 1-36276**

Dear Tracie Mariner and Kevin Vaughn:

We are writing in response to the comment received from the staff of the Division of Corporation Finance (the “Staff”) of the Securities and Exchange Commission by letter dated April 22, 2024 with respect to the above-referenced filing of Ultragenyx Pharmaceutical Inc. (“Ultragenyx” or the “Company”). For your convenience, we have repeated the Staff’s comment before the Company’s response below.

**Form 10-K for Fiscal Year Ended December 31, 2023**  
**Management’s Discussion and Analysis of Financial Condition and Results of Operations, page 69**

1. *Please address the following regarding your table of research and development (R&D) expenses on page 75:*
  - *Tell us and revise your future filings to clearly disclose the extent to which you track any of your R&D expenses at the individual product candidate level, as you previously disclosed in your 2020 Form 10-K.*
  - *If so, revise your future filings to separately quantify your R&D expenses for amounts tracked by product candidate.*
  - *Please provide us with your proposed disclosure in your response.*

**Response:** The Company acknowledges and appreciates the Staff’s comment and respectfully advises the Staff that although the Company does track and allocate certain operational research and development (“R&D”) costs at the individual product candidate level, the Company does not fully track and allocate total R&D expenses at the individual product candidate level.

Specifically, the Company tracks costs to conduct clinical studies, including expenses incurred with clinical research organizations, direct manufacturing costs, and personnel costs such as employee salaries and benefits at the individual product candidate level. Certain other R&D expenses, such as costs associated with Chemistry, Manufacturing and Controls (CMC costs), which are primarily purchases of materials for

our internal gene therapy manufacturing activities, are generally spread across multiple product candidates, and as such are not tracked at the individual product level. As the Company is a diversified commercial company with significant ongoing R&D efforts, potential product candidates are pooled together and resources shared across these candidates as they progress through the R&D pipeline.

In response to the Staff's comment, the Company proposes to include additional disclosure under the subheading " – Research and Development Expenses" in "Management's Discussion and Analysis of Financial Condition and Results of Operations" in the Company's future periodic reports, beginning with the Company's Quarterly Report on Form 10-Q for the three and six months ended June 30, 2024, that includes an additional breakout of operational expenses that are allocable to and analyzed by specific individual product candidates in each product category and additional detail regarding how the Company manages its R&D expenses. The proposed additional disclosure would be substantially in the form set forth on Exhibit A attached hereto. The Company believes the proposed additional disclosure reflects the way management views and manages the Company's R&D activities and business. The Company also believes that the proposed additional disclosure will provide further context to enhance an investor's understanding of the Company's use and expected use of resources in connection with its R&D programs.

\*\*\*

Please advise us if we can provide any further information or assistance to facilitate your review. Please direct any further comments or questions regarding this response letter to the undersigned at [hhorn@ultragenyx.com](mailto:hhorn@ultragenyx.com) or Karah Parschauer, Executive Vice President, Chief Legal Officer & Corporate Affairs at [kparschauer@ultragenyx.com](mailto:kparschauer@ultragenyx.com).

Sincerely,

/s/ Howard Horn

Howard Horn  
Executive Vice President, Chief Financial Officer, Corporate Strategy

cc: Karah Parschauer, Executive Vice President, Chief Legal Officer & Corporate Affairs, Ultragenyx  
Aaron Briggs, Partner, Gibson, Dunn & Crutcher LLP

Page 2 of 3

**Ultragenyx.com**

**Exhibit A**

The below paragraph reflects additional disclosure the Company plans to include, substantially in the form below, as a new third paragraph preceding the table in the section with the sub-heading “ – Research and Development Expenses” in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in the Company’s Quarterly Report on Form 10-Q for the three and six months ended June 30, 2024 and in its future reports.

We manage our research and development expenses by identifying the research and development activities we expect to be performed during a given period and then prioritizing efforts based on anticipated probability of successful technical development and regulatory approval, market potential, available human and capital resources, scientific data and other considerations. We regularly review our research and development activities based on unmet medical need and, as necessary, reallocate resources among our research and development portfolio that we believe will best support the long-term growth of our business. We allocate and analyze certain operational expenses by individual product candidates, specifically costs to conduct clinical studies, including expenses incurred with clinical research organizations, direct manufacturing costs, and salaries and benefits. Other operational expenses are not allocated and analyzed by individual product candidates. For instance, CMC costs, or cost associated with Chemistry, Manufacturing and Controls, are primarily purchases of materials for our internal gene therapy manufacturing activities that qualify as research and development expenses at the time of purchase but for which the allocation and consumption of such costs by a specific product candidate is not determined; accordingly, CMC costs for gene therapy programs are generally spread across multiple product candidates. Although we do track and allocate certain operational R&D costs at the individual product candidate level, as described above and as reflected in the table below, we do not fully track and allocate research and development expenses at the individual product candidate level.

The following table provides a breakout of our research and development expenses by individual product candidate under each major clinical program type and other research and development categories:

Research and Development Expenses (dollars in thousands)

	<u>XXX Months Ended June 30,</u>		<u>Dollar</u> <u>Change</u>	<u>Percent</u> <u>Change</u>
	<u>2024</u>	<u>2023</u>		
Clinical programs:				
Gene therapy programs				
DTX301	\$ XXX	\$ XXX	\$XXX	XX%
DTX401	XXX	XXX	XXX	XX%
UX701	XXX	XXX	XXX	XX%
UX111	XXX	XXX	XXX	XX%
CMC costs	XXX	XXX	XXX	XX%
Biologic and nucleic acid programs				
GTX102	XXX	XXX	XXX	XX%
UX053	XXX	XXX	XXX	XX%
UX143	XXX	XXX	XXX	XX%
Translational research	XXX	XXX	XXX	XX%
Upfront license, acquisition, and milestone fees	XXX	XXX	XXX	XX%
Approved products	XXX	XXX	XXX	XX%
Infrastructure	XXX	XXX	XXX	XX%
Stock-based compensation	XXX	XXX	XXX	XX%
Other research and development	XXX	XXX	XXX	XX%
Total research and development expenses	<u>\$ XXX</u>	<u>\$ XXX</u>	<u>\$XXX</u>	XX%