September 5, 2024

VIA EDGAR Submission

United States Securities and Exchange Commission
Division of Corporation Finance
Office of Life Sciences
100 F Street, N.E.
Washington, D.C. 20549

Attention: Sasha Parikh
Jenn Do

Re: Catalyst Pharmaceuticals, Inc.
Form 10-Q for the period ending June 30, 2024
Filed August 7, 2024
Form 8-K filed February 29, 2024
File No. 001-33057

Dear Sasha Parikh and Jenn Do:

Catalyst Pharmaceuticals, Inc. (the "Company") submits this letter in response to the Staff's comment letter, dated August 16, 2024 regarding (i) the Company's Form 8-K filed on February 29, 2024 (the "Form 8-K") and (ii) the Company's Form 10-Q for the period ending June 30, 2024, filed on August 7, 2024 (the "Form 10-Q"). For your convenience, in this response letter the Company has recited the Staff's comments in boldface type and provided its response to each comment immediately thereafter.

Form 8-K filed February 29, 2024
Exhibit 99.1
Reconciliation of Non-GAAP Metrics, page 9

1. **Please explain to us why you believe that the adjustment to exclude acquired in-process research and development from net income in your reconciliation to non-GAAP Net Income is consistent with Item 10(e) of Regulation S-K or Regulation G, as well as the guidance in Question 100.01 of the *Non-GAAP* Financial Measures Compliance and Disclosure Interpretations.**

While the Company acknowledges and appreciates the Staff's comment, prior to including the cash payment made to Santhera Pharmaceuticals as in-process research and development relating to the Company's acquisition of an exclusive license for North America for vamorolone (the "IPR&D") in the non-GAAP net income reported in the press release that was an exhibit to the Form 8-K, the Company considered the applicable guidance and concluded that the inclusion of the IPR&D was in line with the guidance referenced above and did not cause the Company's non-GAAP financial information reported in the Form 8-K to be misleading.

In making its decision on whether to report the IPR&D in its calculation of non-GAAP net income for 2023 (as reported in the Form 8-K), the Company considered the following factors:

- The acquired IPR&D was not a "normal" operating expense for the Company's research and development activities, but rather was a one-time, up-front payment to acquire a license for a product that was awaiting what was expected to be imminent approval from the U.S. Food and Drug Administration ("FDA"), which product received FDA approval shortly after the closing of the acquisition. The Company notes that it acquired the rights to two products during 2023 (and made up-front cash payments for the rights it acquired in both cases), one of which was already approved by the FDA at the time of acquisition (the purchase price of which is being amortized over the life of the asset) and the other of which was not approved at the time of acquisition but, because of the applicable GAAP acquisition rules, was required to be reported as an R&D expense in the Company's financial statements. Since the accounting for particular acquisitions can vary under GAAP from acquisition transaction to acquisition transaction, depending on the specific facts and circumstances, and in an effort to help investors and analysts compare the Company's performance on an "apples-to-apples" basis, the Company needs to be able to differentiate these payments in the non-GAAP financial information that is provided to the investment community.
- Like other pharmaceutical companies, the Company excludes amortization of intangible assets in its non-GAAP net income calculation, and therefore considering this one-time payment in its calculation of non-GAAP net income is consistent with this practice.
- The Company's business is the marketing of its drug products, of which product acquisitions are an important, but incidental, part of its business. Thus, in 2023, this IPR&D expense was an "infrequent" (or one-time) expense under the circumstances. While there may come a point in the future when up-front payments for product acquisitions will become a "normal" expense of the Company's operations, the Company is not currently at that point.
- The Company is aware that numerous pharmaceutical companies report IPR&D in connection with product acquisitions in their calculation of their non-GAAP net income. The Company presents its non-GAAP net income measures as an alternate measure of performance, consistent with the reporting by other pharmaceutical companies. The Company discloses these amounts because they serve as a type of performance measure utilized by management to evaluate and compare the Company's overall performance. The Company also believes that its reporting on this topic is useful to investors and analysts who follow the Company in their understanding of the Company's financial results, since they want to better understand in evaluating the Company's performance what are normal and recurring R&D expenses and what are significant, but infrequent, up-front payments made in connection with product acquisitions. Finally, the Company fully explains in the press release that is an exhibit to the Form 8-K which components from the Company's statement of operations are included in the reconciliation comparing the Company's GAAP and non-GAAP net income so that the presentation is not misleading.

Under the circumstances, the Company believes that its decision to exclude the acquisition IPR&D from net income in its reconciliation to non-GAAP net income for 2023 was appropriate in accordance with applicable guidance and is not misleading.

Form 10-Q for the period ending June 30, 2024
Management's Discussion and Analysis of Financial Condition and Results of Operations
Results of Operations
Research and Development Expenses, page 39

2. You noted that you expect research and development expenses will continue to be significant in 2024 and beyond as you execute on your strategic initiative and portfolio expansion efforts. You state that research and development expenses for the three and six months ended June 30, 2024 primarily consisted of costs relating to research and development activities supporting your commercial products. We believe your disclosures could be improved by expanding your discussion in future filings with regards to the commercial product and the types of activities you are referring to. In addition, providing a table that breaks out your R&D expense by each of the major components you note on page 39 and/or by product candidate will also provide a better understanding of your research and development expenses. Please provide revised disclosure to be provided in future filings.

The Company believes its disclosure is sufficient, particularly under circumstances in which the total amount of R&D expenses (outside the IPR&D discussed in question 1 above) is not material for any of the periods presented. However, after considering the Staff's comment, the Company agrees that going forward and beginning with its Form 10-Q for the quarterly period ended September 30, 2024, the Company will add more detail to its R&D table to better explain the various categories of its R&D spending. In that regard, attached ***Exhibit "A"*** to this response letter illustrates how this information would have been presented had the Form 10-Q for the second quarter ended June 30, 2024 included this more detailed disclosure.

Further, as the Company has publicly reported, the Company hopes to acquire the rights to additional products in the future, some of which may be in earlier stages of development than the products that the Company has acquired to date. While to this date no contracts have been entered into for additional acquisitions, if the Company does make future acquisitions, it expects that its R&D expenses may increase (possibly in a significant amount). That is the reason for the use of the word "significant" in the Company's disclosure in its MD&A discussion on this topic. The language in ***Exhibit "A"*** illustrates how the Company intends to provide more clarity on its use of the word "significant" in its future filings.

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The Company acknowledges that it and its management are responsible for the accuracy and adequacy of its disclosures, notwithstanding any review, comments, action, or absence of action by the Staff.

Thank you for your continued assistance with this filing. If you have any questions, please call me at (305) 420-3200 or our counsel, Philip Schwartz at Akerman LLP at (954) 468-2455.

Sincerely,

CATALYST PHARMACEUTICALS, INC.

/s/ Michael W. Kalb
Michael W. Kalb
Executive Vice President and Chief Financial Officer

cc: Richard J. Daly
President and Chief Executive Officer
Catalyst Pharmaceuticals, Inc.

Philip B. Schwartz, Esq.
Akerman LLP

Exhibit A

Research and Development Expenses.

Research and development expenses for the three months ended June 30, 2024 and 2023 were approximately $3.0 million and $4.0 million, respectively, and represented approximately 4% and 7% of total operating costs and expenses, respectively. Research and development expenses for the three months ended June 30, 2024 and 2023 were as follows (in thousands):

	For the Three Months Ended June 30,		Change	
	2024	2023	$	%
Salary and benefit expense	$ 1,356	$ 846	510	60.3
Employee stock-based compensation expense	403	351	52	14.8
Research and clinical trial expense	858	1,964	(1,106)	(56.3)
Additional research and development expense	368	793	(425)	(53.6)
Total research and development expenses	$ 2,985	$ 3,954	(969)	(24.5)

Research and development expenses for the six months ended June 30, 2024 and 2023 were approximately $5.6 million and $7.5 million, respectively, and represented approximately 4% and 7% of total operating costs and expenses, respectively. Research and development expenses for the six months ended June 30, 2024 and 2023 were as follows (in thousands):

	For the Six Months Ended June 30,		Change	
	2024	2023	$	%
Salary and benefit expense	$ 2,099	$ 1,701	398	23.4
Employee stock-based compensation expense	912	690	222	32.2
Research and clinical trial expense	1,995	3,977	(1,982)	(49.8)
Additional research and development expense	560	1,148	(588)	(51.2)
Total research and development expenses	$ 5,566	$ 7,516	(1,950)	(25.9)

Research and development expenses remained relatively consistent for the three and six months ended June 30, 2024, when compared to the same periods in 2023. For the three and six months ended June 30, 2024, research and development expenses primarily consisted of costs relating to development activities supporting our commercial products. For the three and six months ended June 30, 2023, research and development expenses also included costs relating to closing out sites for both our MuSK-MG clinical trial and our previously operated expanded access program, as well as costs for development activities supporting our commercial products.

We are continuing to focus our business development efforts on acquiring additional drug products that are (or may be, if approved) used to treat rare and difficult to treat diseases. If we make future acquisitions of products in earlier stages of development, or if we determine to evaluate products already approved for the treatment of additional indications or additional diseases, we expect that our R&D expenses during such future periods will become more significant.