January 10, 2022

By EDGAR submission
Division of Corporation Finance
Office of Life Sciences
United States Securities and Exchange Commission
100 F Street N.E.
Washington, D.C. 20549
Attention: Angela Connell
Li Xiao

Re: Eli Lilly & Co
Form 10-K for the Fiscal Year Ended December 31, 2020
Filed February 17, 2021
Form 8-K furnished October 26, 2021
File No. 001-06351

Dear Angela Connell and Li Xiao,

Eli Lilly and Company (Lilly, we or us) respectfully submits this letter in response to the comment received from the staff (the Staff) of the United States Securities and Exchange Commission by letter dated December 9, 2021 in relation to the above-referenced filings. For ease of reference, we repeat the Staff's comment prior to our response.

Form 8-K furnished October 26, 2021
Exhibit 99.1 Earnings Release
Reconciliation of GAAP Reported to Selected Non-GAAP Adjusted Information (Unaudited), Page 26

1. You include acquired in-process research and development as one of your non-GAAP adjustments and state that these costs were associated with upfront payments for acquired in-process research and development projects acquired in a transaction other than a business combination. You also include a similar non-GAAP adjustment in your earnings release for the year ended December 31, 2020. Please address the following:

   - For each asset acquisition for which you recorded acquired IPR&D in 2020 and the nine months ended September 30, 2021, clarify for us whether you acquired the associated research & development project outright or acquired the rights to the product candidate and/or related technology under a license agreement. In this regard, we note disclosures in both your Form 10-K for the year ended December 31, 2020, and your Form 10-Q for the quarterly period ended September 30, 2021 that appear to distinguish between acquisitions and business development transactions or other collaborations.

   - For each type of acquired IPR&D transaction (i.e., asset acquisitions, license agreements, etc.), explain to us why you believe it is appropriate to include non-GAAP adjustments for these upfront payments given that these expenditures appear to be normal, recurring, cash operating expenses necessary to operate your business. Refer to Question 100.01 of the Non-GAAP Financial Measures Compliance and Disclosure Interpretations.

Response:

Our business development transactions pursuant to which we acquire rights to externally developed IPR&D projects are generally acquisitions or licensing agreements. Regardless of the form of the transaction, we recognize acquired IPR&D for the initial costs of externally developed IPR&D projects acquired directly in a transaction as an asset acquisition if the transaction does not meet the definition of a business in accordance with Accounting Standards Codification (ASC) 805, *Business Combinations*. For certain license agreements, we may collaborate with the licensor in the development and/or commercialization of the acquired IPR&D project(s).

Of the 17 asset acquisitions for which we recorded acquired IPR&D for the year ended December 31, 2020 and the nine months ended September 30, 2021, three were IPR&D projects acquired outright via acquisition of an entity. The remaining 14 asset acquisitions were acquired under license agreements. The form of transaction for each asset acquisition for which we recorded acquired IPR&D charges for the year ended December 31, 2020 and the nine months ended September 30, 2021, is described below:

Counterparty	Acquisition Month	Phase of Development	Acquired IPR&D Charge*	Form of Transaction
Sitryx Therapeutics Limited	March 2020	Pre-clinical	$52.3	In-license agreement
AbCellera Biologics Inc.	March 2020	Pre-clinical	25.0	In-license agreement
Shanghai Junshi Biosciences Co., Ltd.	May 2020	Pre-clinical	20.0	In-license agreement
Petra Pharma Corporation	May 2020	Pre-clinical	174.8	Acquisition of an entity
Evox Therapeutics Limited	June 2020	Pre-clinical	22.0	In-license agreement
Innovent Biologics, Inc.	October 2020	Phase III	200.0	In-license agreement
Disarm Therapeutics, Inc.	October 2020	Pre-clinical	126.3	Acquisition of an entity
Fochon Pharmaceuticals, Ltd.	November 2020	Pre-clinical	40.0	In-license agreement
Precision Biosciences, Inc.	January 2021	Pre-clinical	107.8	In-license agreement
Merus N.V.	January 2021	Pre-clinical	46.5	In-license agreement
Asahi Kasei Pharma Corporation	January 2021	Phase I	20.0	In-license agreement
Rigel Pharmaceuticals, Inc.	March 2021	Phase I	125.0	In-license agreement
MiNA Therapeutics Limited	May 2021	Pre-clinical	25.0	In-license agreement
Protomer Technologies Inc.	July 2021	Pre-clinical	57.3	Acquisition of an entity
Kumquat Biosciences Inc.	July 2021	Pre-clinical	55.0	In-license agreement
Lycia Therapeutics, Inc.	August 2021	Pre-clinical	35.0	In-license agreement
ProQR Therapeutics N.V.	September 2021	Pre-clinical	26.7	In-license agreement

*: Presented in millions

Regardless of the form of the transaction, we do not believe these acquired IPR&D charges are normal, recurring, cash operating expenses necessary to operate our business whose exclusion from our non-GAAP financial measures is prohibited under Rule 100(b) of Regulation G and Question 100.01 of the Non-GAAP Financial Measures Compliance and Disclosure Interpretations. We believe it is appropriate to include non-GAAP adjustments for these acquired IPR&D charges given these expenditures are our initial investments in external innovation and are highly variable and difficult to predict and for the other reasons described below. We do not believe these non-GAAP adjustments are misleading. Rather, by providing this information to investors, it assists investors in making meaningful period-over-period comparisons and in identifying operating trends that would otherwise be masked or distorted by acquired IPR&D charges.

Acquired IPR&D charges are initial "buy-in" investments to acquire rights to externally developed IPR&D projects and are excluded from operating cash flows

When we incur acquired IPR&D charges we are making an initial "buy-in" investment in an externally developed IPR&D project. This initial investment in an externally developed IPR&D project is different than normal, recurring, cash operating expenses to operate our business, and therefore, we classify acquired IPR&D as a separate line on our consolidated statement of operations. Accordingly, in our consolidated statement of cash flows we classify acquired IPR&D as investing cash flows, not operating cash flows. This "buy-in" investment is not based on the amount of historical research and development effort incurred up to the acquisition date for a specific IPR&D project, but rather represents a negotiated fair value of the rights to the specific externally developed IPR&D being transferred to us based upon market expectations and risk of it becoming a successful new product. The negotiated fair value is often a result of a highly competitive process with other market participants to determine the amount necessary to buy into that particular IPR&D project. It is common for the "buy-in" investment to be significantly more than the amount of historical research and development effort incurred up to the acquisition date by the acquiree for a specific externally developed IPR&D project. We believe once we have acquired the rights to an IPR&D project and it is part of our pipeline, the continued development of that asset over many years is part of our normal, recurring, cash operating expenses to operate our business. Accordingly, those ongoing costs are included in our research and development expenses on our consolidated statement of operations and are included in our operating cash flows on our consolidated statement of cash flows. We have not made non-GAAP adjustments for the further development of any of these acquired IPR&D projects.

We have significant normal, ongoing research and development expenses

We are engaged in numerous research and development programs, primarily internally-originated research and development projects. Our research and development expenses have been significantly more than our acquired IPR&D annually and include the ongoing normal, recurring operating expenses for internally-originated research and development programs and for externally-originated research and development programs that are incurred subsequent to our "buy-in" investment. While we will likely incur acquired IPR&D charges in the future as we identify external innovation that aligns with our strategy and is an opportunistic "buy-in" investment, identifying external innovation is not crucial to our business as demonstrated by the fact that the majority of our consolidated revenue is from products that are a result of internally-originated research and development projects, including our currently most successful product.

Acquired IPR&D charges are highly variable and difficult to predict

We adjust our GAAP financial results to exclude acquired IPR&D as these items are typically highly variable, difficult to predict, and/or of a size that could have a substantial impact on our reported operations for a period. While these items do occur from time to time, their timing and magnitude in any given period are unpredictable. Our business development transactions are very difficult to predict as to the size, timing, and even the possibility of closing, as negotiations typically span over multiple quarters and are often highly competitive. We do not plan or budget for acquired IPR&D charges in our normal planning/budgeting process. In order to demonstrate how significant and unpredictable our acquired IPR&D charges can be, following is a table that reflects our most recent acquired IPR&D charges by quarter and year (in millions):

Year	Three Months Ended				Year to Date
	March 31	June 30	September 30	December 31	
2021	$299.3	$25.0	$174.0	Not Available	$498.3*
2020	52.3	241.8	-	366.3	660.4
2019	136.9	25.0	77.7	-	239.6
2018	-	1,624.5	30.0	329.4	1,983.9

*:Represents nine months ended as fourth quarter information is not yet available.

We believe by making adjustments for acquired IPR&D in our non-GAAP financial measures, it provides useful information for investors that supplements our GAAP financial results as this excludes these highly unpredictable, volatile items, which allows for a better analysis of our core business activities.

We believe this is how investors look at our business

We believe that our non-GAAP financial measures provide useful information to investors. Among other things, they help investors evaluate our ongoing operations. A number of our investors have expressed that they support the designation of these discrete acquired IPR&D charges as non-GAAP adjustments. Inclusion of these discrete acquired IPR&D charges as non-GAAP adjustments gives investors the opportunity to analyze results excluding the impact of the "buy-in" investment and assist in making meaningful period-over-period comparisons of our core business. Otherwise, the "buy-in" investment can create analytical challenges by masking or distorting operating trends of our core business. We believe adjusting for acquired IPR&D in our non-GAAP financial measures is not misleading to investors.

Adjusting for upfront charges related to acquired IPR&D as part of non-GAAP financial measures is prevalent across the pharmaceutical industry. Many pharmaceutical companies invest in external innovation as part of their strategy to enhance their pipeline, and they also treat these items as adjustments to non-GAAP financial measures. Some of our peers report their financial results in accordance with International Financial Reporting Standards (IFRS). Under IFRS, an entity is permitted to capitalize the upfront charges related to acquired IPR&D in an asset acquisition. Our adjustment for the "buy-in" investment related to acquired IPR&D as part of non-GAAP financial measures allows more comparability of financial results among our peers, including companies reporting under IFRS.

Without this non-GAAP adjustment, management's ability to communicate our results of operations and guidance would be substantially more difficult

Our non-GAAP financial measures can also assist in making meaningful period-over-period comparisons and in identifying operating trends that would otherwise be masked or distorted by the items subject to the adjustments. By not adjusting for these acquired IPR&D charges on a non-GAAP basis, we are uncertain how we would continue to give meaningful financial guidance on a non-GAAP basis to the investor community since we are unable to forecast these "buy-in" investments within a reasonable degree of certainty given the variability and difficulty in predicting these discrete charges. We may need to update financial guidance on irregular intervals as a result of these transactions. It is also plausible that we may no longer provide guidance to the investor community if we didn't have the ability to adjust for these "buy-in" investments in our non-GAAP financial measures.

We believe it is appropriate to include non-GAAP adjustments for acquired IPR&D charges given these expenditures are our "buy-in" investments in external innovation and are highly variable and difficult to predict. We view these "buy-in" investments as an investing activity, not an operating activity. In addition, adjusting for upfront charges related to acquired IPR&D as part of non-GAAP financial measures allows for more comparability across the pharmaceutical industry, including our peers that report their financial results in accordance with IFRS. Based upon these factors and our consideration of Question 100.01 of the Non-GAAP Financial Measures Compliance and Disclosure Interpretations, we do not believe this adjustment to be misleading.

If you have any questions about this response or require additional information, please contact me at 317-651-2310. We would welcome a conversation on this matter as we sincerely believe we are providing decision useful information to the readers of our financials.

Sincerely yours,

Eli Lilly and Company

By: /s/ Donald A. Zakrowski
Vice President, Finance, and Chief Accounting Officer