REGENERON

Regeneron Pharmaceuticals, Inc.
777 Old Saw Mill River Road
Tarrytown, NY 10591-6707

Phone 914 847 7000
www.regeneron.com

May 20, 2024

VIA EDGAR

U.S. Securities and Exchange Commission
Division of Corporation Finance
Office of Life Sciences
100 F Street, NE
Washington, D.C. 20549
Attn: Franklin Wyman and Angela Connell

Re: Regeneron Pharmaceuticals, Inc.
Form 10-K for the Fiscal Year Ended December 31, 2023
Filed February 5, 2024
File No. 000-19034

Dear Mr. Wyman and Ms. Connell:

This letter sets forth the responses of Regeneron Pharmaceuticals, Inc. (the "Company," "Regeneron," "we," "us," and "our") to the comments of the staff (the "Staff") of the U.S. Securities and Exchange Commission (the "Commission") set forth in the Staff's letter dated May 8, 2024, with respect to the above-referenced Annual Report on Form 10-K filed on February 5, 2024 (the "2023 Form 10-K").

Set forth below in bold are the headings and text of the Staff's comments followed by the Company's response.

Form 10-K for the Fiscal Year Ended December 31, 2023

Item 1. Business
Products, page 3

1. Please address the following as it relates to your presentation of net product sales of Regeneron-discovered products on page 5:

- **Explain the purpose of this disclosure and its usefulness to investors.**

Response:

Regeneron is a fully integrated biotechnology company whose primary business is developing intellectual property ("IP") and monetizing Company-developed IP through its own commercialization, commercialization by collaborators, and licensure to third parties. The table of net product sales of Regeneron-discovered products demonstrates the Company's ability to innovate, discover and develop new products, and bring those products to market either alone or based on contractual arrangements with other parties. The table also shows the degree to which the Company, a collaborator, and/or a licensee is currently commercializing the products discovered by Regeneron. In arrangements where the Company's collaborator or licensee is currently commercializing such products and is recording net product sales as a result, the Company records its share of profits and/or royalties on such sales in Collaboration revenue or Other revenue, as applicable.

In addition, as noted in Part I. Item 1A. "Risk Factors" and Part II. Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations" of the 2023 Form 10-K, the Company is substantially dependent on the success of EYLEA® (aflibercept) Injection, EYLEA® HD (aflibercept) Injection 8 mg, and Dupixent® (dupilumab) (both in jurisdictions in which Regeneron records net product sales and jurisdictions in which a collaborator records net product sales of such products); therefore, we believe disclosing total net product sales of these products (as well as the other products listed in the table), regardless of the party recording such net product sales, provides useful context for investors.

- **Disclose more prominently that not all of the net product sales presented on page 5 are recognized as revenue in your Statements of Operations.**

Response:

We direct the Staff to the top of page 5 of the 2023 Form 10-K, which contains the following disclosure:

> "Note: Refer to table below (net product sales of Regeneron-discovered products) for information regarding whether net product sales for a particular product are recorded by us or others . . . "

In future filings, we will also include similar disclosure in the lead-in to the table presenting net product sales of Regeneron-discovered products as follows:

> "The table below includes net product sales of Regeneron-discovered products. Such net product sales are recorded by us or others, as further described in the footnotes to the table."

- **For those net product sales recorded by a collaboration partner and for which you record your share of profits in connection with the collaboration, quantify the amounts recorded and specify where such amounts are recorded on your Statements of Operations (i.e., collaboration revenue).**
- **Provide cross-references to your revenue disclosure for each collaboration in MD&A.**

Response:

To the extent that net product sales presented in the table of net product sales of Regeneron-discovered products are recorded by a collaborator or licensee, we will specify in future filings where our share of profits or royalties on such sales are recorded within our Statements of Operations (i.e., within Collaboration revenue or Other revenue). In addition, to the extent that our share of profits or royalties are separately disclosed in the MD&A because they are deemed to be material, we will include a cross-reference to the relevant disclosure. Accordingly, in future filings, we will amend relevant footnotes to the table presenting net product sales of Regeneron-discovered products to read as follows (changes are noted in italics):

(a) Regeneron records net product sales of EYLEA HD and EYLEA in the United States, and Bayer records net product sales outside the United States. The Company records its share of profits in connection with sales outside the United States *within Collaboration revenue. Refer to Part II, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations - Results of Operations - Revenues - Bayer Collaboration Revenue" for such amounts.*

(b) Sanofi records global net product sales of Dupixent and Kevzara. The Company records its share of profits in connection with global sales of Dupixent and Kevzara *within Collaboration revenue. Refer to Part II, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations - Results of Operations - Revenues - Sanofi Collaboration Revenue" for such amounts.*

(d) Regeneron records net product sales of Praluent in the United States. Sanofi records net product sales of Praluent outside the United States, and pays the Company a royalty on such sales, *which is recorded within Other revenue*.

(e) Roche records net product sales of Ronapreve outside the United States, and the parties share gross profits from sales, *which are recorded within Collaboration revenue*. *Refer to Part II, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations - Results of Operations - Revenues - Roche Collaboration Revenue" for such amounts.*

Notes to the Consolidated Financial Statements
3. Collaboration, License and Other Agreements
a. Sanofi, page F-17

2. We note your disclosure on page 89 that under your collaboration agreements with Bayer and Sanofi, you have contingent contractual obligations to reimburse Bayer and Sanofi for a defined percentage of agreed-upon development expenses funded by Bayer and Sanofi (i.e., "development balance") if the applicable collaboration is profitable. You also disclose that these reimbursements are deducted each quarter, in accordance with a formula, from your share of the collaboration profits otherwise payable to you. Please address the following specifically as it relates to your contingent reimbursement obligation under the Sanofi Antibody License and Collaboration Agreement ("LCA"):

- **Describe and quantify the contractual terms governing your contingent reimbursement obligation under the LCA and the methods and key assumptions used to determine the associated $2.33 billion contingent obligation as of December 31, 2023.**

Response:

We believe the existing disclosure contained in Part I, Item 1. "Business - Collaboration, License, and Other Agreements - Sanofi - Antibody" of the 2023 Form 10-K (which is also included in Note 3 on page F-17) describes the key terms governing our contingent reimbursement obligations (see excerpt below). In future filings, the Company will clarify that the July 1, 2022 amendment to the Antibody License and Collaboration Agreement (the "Antibody LCA") was entered into in connection with the Company's acquisition of exclusive worldwide rights to Libtayo described further below in this letter (changes to future filings are noted in italics).

> "Under the terms of the Antibody License and Collaboration Agreement (the "LCA"), Sanofi is generally responsible for funding 80% to 100% of agreed-upon development costs. We are obligated to reimburse Sanofi for 30% to 50% of worldwide development expenses that were funded by Sanofi based on our share of collaboration profits from commercialization of collaboration products. Under the terms of the LCA, we were required to apply 10% of our share of the profits from the Antibody Collaboration in any calendar quarter to reimburse Sanofi for these development costs. On July 1, 2022, an amendment to the LCA, *which had been entered into in connection with our acquisition of exclusive worldwide rights to Libtayo, became effective. Pursuant to this amendment,* the percentage of Regeneron's share of profits used to reimburse Sanofi for such development costs *has* increased from 10% to 20%."

The development balance as of the end of a quarter is contractually defined in the Antibody LCA (previously filed as an exhibit and listed as Exhibit 10.10 to the 2023 Form 10-K) as "(a) fifty percent (50%) of the aggregate amount of Development Costs incurred by both Parties under the Global Development Plan for all Licensed Products from the Effective Date through the close of such Quarter, excluding any Shared Phase 3 Trial Costs, plus (b) thirty percent (30%) of the aggregate amount of Shared Phase 3 Trial Costs incurred by both Parties under the Global Development Plans for all Licensed Products from the Effective Date through the close of such Quarter, less (c) the aggregate amount of Development Compensation Payments included in the calculation of the Quarterly True-Up in all prior Quarters."

As it relates to the $2.33 billion contingent obligation as of December 31, 2023, we note that the method of calculation is also contractually specified. In addition, the inputs necessary to calculate the development costs incurred and the development balance (i.e., the funding percentages described in the preceding paragraph and the percentage used to calculate the Company's quarterly repayment of the development balance (currently defined as 20% of Regeneron's share of profits)) come directly from the accounting records of the Company and Sanofi each quarter or are similarly contractually specified. Consequently, given the nature of these inputs and the contractually specified formula, no assumptions were used to determine the associated $2.33 billion contingent obligation as of December 31, 2023. In addition, Regeneron and Sanofi reconcile the contingent obligation balance with each other on a quarterly basis.

- **Clarify why the $2.33 billion contingent repayment obligation does not appear to be recorded as a liability on your balance sheet. In particular, explain your basis for deeming the obligation to be contingent given the likelihood of continued profits under the Antibody LCA.**

Response:

We account for arrangements deemed to be collaborations, including the collaboration governed by the Antibody LCA, in accordance with ASC 808, *Collaborative Arrangements*. In accordance with ASC 808, parts of a collaborative arrangement that are within the scope of other authoritative literature shall be accounted for using the relevant provisions of that literature. Accordingly, the Company utilized the guidance in ASC 730, *Research and development expense*, to determine the appropriate recognition of amounts received from parties who fund our research and development costs which are subject to potential repayment. We note the following guidance pursuant to ASC 730-20 related to research and development arrangements:

> **25-2** An entity shall determine the nature of the obligation it incurs when it enters into an arrangement with other parties who fund its research and development . . .
>
> **25-3** If the entity is obligated to repay any of the funds provided by the other parties regardless of the outcome of the research and development, the entity shall estimate and recognize that liability. This requirement applies whether the entity may settle the liability by paying cash, by issuing securities, or by some other means.
>
> **25-4** To conclude that a liability does not exist, the transfer of the financial risk involved with research and development from the entity to the other parties must be substantive and genuine. To the extent that the entity is committed to repay any of the funds provided by the other parties regardless of the outcome of the research and development, all or part of the risk has not been transferred. The following are some examples in which the entity is committed to repay:
>
> a. The entity guarantees, or has a contractual commitment that assures, repayment of the funds provided by the other parties regardless of the outcome of the research and development.
> b. The other parties can require the entity to purchase their interest in the research and development regardless of the outcome.
> c. The other parties automatically will receive debt or equity securities of the entity upon termination or completion of the research and development regardless of the outcome.
>
> **25-5** Even though the written agreements or contracts under the arrangement do not require the entity to repay any of the funds provided by the other parties, surrounding conditions might indicate that the entity is likely to bear the risk of failure of the research and development. If those conditions suggest it is probable that the entity will repay any of the funds regardless of the outcome of the research and development, there is a presumption that the entity has an obligation to repay the other parties. That presumption can be overcome only by substantial evidence to the contrary. In this context, probable means that repayment is likely.
>
> **25-6** Examples of conditions leading to the presumption that the entity will repay the other parties include any of the following:
>
> a. The entity has indicated an intent to repay all or a portion of the funds provided regardless of the outcome of the research and development.
> b. The entity would suffer a severe economic penalty if it failed to repay any of the funds provided to it regardless of the outcome of the research and development. An economic penalty is considered severe if in the normal course of business an entity would probably

choose to pay the other parties rather than incur the penalty. For example, an entity might purchase the partnership's interest in the research and development if the entity had provided the partnership with proprietary basic technology necessary for the entity's ongoing operations without retaining a way to recover that technology, or prevent it from being transferred to another party, except by purchasing the partnership's interest.

c. A significant related party relationship between the entity and the parties funding the research and development exists at the time the entity enters into the arrangement.
d. The entity has essentially completed the project before entering into the arrangement.

Upon entering into the original Antibody LCA in 2007 (which, in accordance with ASC 730-20-25-2, was the time as of which we were to determine the nature of the obligation to repay Sanofi a portion of the research and development costs funded by Sanofi), the products under the collaboration were in preclinical or early-stage clinical development. At such time, we concluded that there was a substantive and genuine transfer of risk (i.e., it was not probable that research and development costs funded by Sanofi would be repaid by the Company given the risk and uncertainty as to whether any products subject to the Antibody LCA would be approved; and, if approved, whether any such products would generate profits). Therefore, we did not record a liability related to the contingent repayment obligation (i.e., "development balance").

On July 1, 2022, pursuant to an amendment to the Antibody LCA in conjunction with the acquisition of exclusive worldwide rights to Libtayo described further below in this letter, the percentage of the Company's share of profits used to reimburse Sanofi for previously funded development costs increased from 10% to 20%. As a result of this modified arrangement, we determined it was necessary to assess whether it was probable that research and development costs funded prospectively by Sanofi (which are subject to repayment) after the modification would ultimately be repaid. In performing such assessment, we considered the guidance in ASC 730-20 as well as the factors below as of July 1, 2022:

- Each of Dupixent and Kevzara® (sarilumab) had received regulatory approval, and each of these products had been developed under the collaboration governed by the Antibody LCA (the "Antibody Collaboration") and was being commercialized thereunder.
- At the time the modified arrangement became effective in July 2022, the Antibody Collaboration was profitable. For example, for the fiscal year ended December 31, 2021 (i.e., the most recent fiscal year prior to the modification), the Company's share of collaboration profits in connection with the commercialization of Dupixent and Kevzara, prior to any development balance repayment, was $1.511 billion).
- Our forecast related to the Antibody LCA illustrated the continued anticipated profitability of the Antibody Collaboration.

Based on the information above, as of the date of the modification of the arrangement (i.e., July 1, 2022), we concluded that any future Antibody Collaboration research and development costs funded by Sanofi (i.e., funded after July 1, 2022) would not represent a substantive and genuine transfer of risk (i.e., it was probable that research and development costs funded by Sanofi would be repaid by the Company); and, as a result, we determined it was appropriate to recognize a liability each quarter thereafter equal to the amount of funding the Company is obligated to repay in respect of such quarter (i.e., the quarterly increase to the development balance).

In future filings, we will include additional disclosure in the notes to the financial statements to clarify our basis of accounting for research and development funding arrangements as follows:

When the Company enters into or modifies an arrangement with a party to fund its research and development costs, the Company considers whether the costs that it may be obligated to repay represent a liability within the scope of ASC 730-20, Research and development expenses. If the Company concludes that such funding does not represent a substantive and genuine transfer of risk, a liability will be recorded.

In addition, to the extent that a material liability related to the Antibody Collaboration development balance has been recorded as of the balance sheet date, we would disclose such amount within our existing tabular disclosure of contract balances with Sanofi (in the applicable note of our financial statements included in the relevant periodic report).

- **Clarify your basis for reporting certain reimbursements of Sanofi development expenses as R&D expense, while reporting other such reimbursements as a reduction of collaboration profits. For example, if true, confirm that the $83.7 million in R&D expenses classified as "Regeneron's obligation for its share of Sanofi R&D expenses, net of reimbursement of R&D expenses" on page F-17 represents your share of current period R&D expenses incurred by Sanofi based on the original expense sharing percentage in the LCA, while the $459.8 million reported on page 80 as "Reimbursement of development expenses incurred by Sanofi in accordance with Regeneron's payment obligation" represents reimbursements of amounts due under your contingent repayment obligation which relates to cumulative development costs.**

Response:

The guidance in ASC 808 is not prescriptive on the specific presentation of inflows from collaborators and continues to permit entities to classify transactions in a collaborative arrangement that are outside the scope of other guidance, including ASC 606, *Revenue from Contracts with Customers*, based on an analogy to other US GAAP guidance, or a reasonable, rational, and consistently applied policy election, if there is no appropriate analogy.

We considered the below guidance within ASC 808-10:

> **45-3** Parts of a collaborative arrangement that are within the scope of other authoritative accounting literature in accordance with paragraph 808-10-15-5A shall be presented using the relevant provisions of that literature. If parts of the arrangement are outside the scope of other authoritative accounting literature, the presentation of those parts shall be based on an analogy to authoritative accounting literature or if there is no appropriate analogy, a reasonable, rational, and consistently applied accounting policy election. An entity shall evaluate the presentation of parts of a collaborative arrangement on the basis of the nature of the arrangement, the nature of its business operations, and the contractual terms of the arrangement. For example, if one party to an arrangement is required to make a payment to the other party to reimburse a portion of that party's research and development costs, that portion of the net payment may be classified as research and development expense in the payor's financial statements in accordance with Topic 730. An entity is precluded from presenting transactions in a collaborative arrangement together with revenue from contracts with customers unless the entity applies the guidance in Topic 606 to a unit of account that is within the scope of that Topic in accordance with paragraph 808-10-15-5B.

As disclosed in Note 1 to the Consolidated Financial Statements included in the 2023 Form 10-K, in arrangements where the Company does not deem its collaborator to be its customer, payments to and from such collaborator are presented in the Company's statement of operations based on the nature of our

business operations, the nature of the arrangement, including the contractual terms, and the nature of the payments.

Accordingly, we confirm the following:

- The $83.7 million in R&D expenses classified as "Regeneron's obligation for its share of Sanofi R&D expenses, net of reimbursement of R&D expenses" on page F-17 represents our share (net) of current period research and development expenses incurred by both parties during the fiscal year ended December 31, 2023 based on (i) the original expense sharing percentages in the Antibody LCA, and (ii) the amount of the research and development costs funded by Sanofi for the current period that we have deemed to be probable of repayment (as described above). Such amount is recorded within Research and development expenses on our Statements of Operations.
- The $459.8 million reported on page 80 as "Reimbursement of development expenses incurred by Sanofi in accordance with Regeneron's payment obligation" represents reimbursements of amounts due to Sanofi under our contingent repayment obligation related to cumulative development costs incurred prior to July 1, 2022. Such amount, which is contractually specified as a reduction to our share of profits in connection with the Antibody LCA, is recorded as a reduction to Collaboration revenue within our Statements of Operations.

- **Clarify your disclosure on page F-17 that a portion of the value associated with the increase in reimbursement percentage (from 10% to 20%) was deemed to be contingent consideration attributable to your acquisition of the Libtayo (cemiplimab) rights under the IO LCA, which will be recorded as an increase to the Libtayo intangible asset over time as you repay such development costs to Sanofi. Cite the relevant accounting guidance supporting this accounting treatment.**

Response:

In considering the accounting for the increase in reimbursement percentage from 10% to 20%, we note that this modification to the Antibody LCA was negotiated and entered into in connection and concurrently with the July 1, 2022 Amended and Restated Immuno-oncology License and Collaboration Agreement ("IO LCA") with Sanofi, pursuant to which we obtained the exclusive worldwide rights to Libtayo. Therefore, we concluded this modification to the Antibody LCA represented additional consideration transferred by the Company to Sanofi to acquire the exclusive worldwide rights to Libtayo.

The transaction to acquire the exclusive worldwide rights to Libtayo was accounted for by the Company as an asset acquisition. As the increase in the reimbursement percentage from 10% to 20% represented solely an acceleration of the development balance repayment, rather than a change in the total amount that Sanofi would ultimately receive, we deemed the net present value differential when comparing the 10% repayment rate versus the 20% repayment rate to be the incremental contingent consideration/value the Company was paying to acquire the exclusive worldwide rights to Libtayo.

We considered the following interpretive guidance within the PwC *Property, plant, and equipment and other assets* accounting guide related to contingent consideration in an asset acquisition:

> **2.3.3 Contingent consideration arrangements (asset acquisitions)**
>
> Asset acquisitions may include contingent consideration, which represents an obligation of the acquirer to transfer additional assets or equity interests to the seller if future events occur or

conditions are met. Obligations of the acquirer to transfer additional assets or equity interests based only upon the passage of time do not represent contingent consideration and instead may represent seller financing.

There is no specific guidance within ASC 805-50 for the recognition and measurement of contingent consideration obligations in an asset acquisition. We believe that contingent consideration in an asset acquisition that is not accounted for under other US GAAP (e.g., as a derivative under ASC 815) should be recognized when probable and reasonably estimable, by analogy to ASC 450-20.

Contingent consideration recognized should be included in the initial cost of the assets acquired. Subsequent changes in the recorded amount of contingent consideration should generally be recognized as an adjustment to the cost basis of the acquired assets, by analogy to ASC 323-10-35-14A and ASC 360-10-30-1. These subsequent changes should be allocated to the acquired assets based on their relative fair value at the date of acquisition.

A change in contingent consideration impacts the cost basis of acquired assets, which may also impact the income statement through subsequent accounting for the acquired asset. We are aware of diversity in practice regarding the subsequent treatment of the income statement effect of changes to the cost basis of the acquired assets. We generally believe the depreciation or amortization of these assets should be recognized as a cumulative "catch up" adjustment, as if the additional amount of consideration that is no longer contingent had been accrued from the outset of the arrangement.

Thus, each quarter, as the development balance repayment is recorded, we also record an addition to the Libtayo intangible asset (as this is additional contingent consideration being provided to Sanofi related to the acquisition of exclusive worldwide rights to Libtayo) related to the net present value of the incremental repayment amount. An excerpt of our policy, as disclosed in Note 1 of the Consolidated Financial Statements included in the 2023 Form 10-K, is as follows:

"Payments to acquire intangible assets in an asset acquisition may include up-front payments and contingent consideration. With regard to contingent consideration in an asset acquisition, the Company recognizes regulatory milestones upon achievement, royalties in the period in which the underlying sales occur, and sales-based milestones when the milestone is deemed probable by the Company of being achieved. If contingent consideration is recognized subsequent to the acquisition date in an asset acquisition, the amount of such consideration is recorded as an addition to the cost basis of the intangible asset with a cumulative catch-up adjustment for amortization expense as if the additional amount of consideration had been accrued from the outset of the acquisition."

In future filings, we will amend our disclosure in Note 3 of the Consolidated Financial Statements included in the relevant periodic report as follows (changes are noted in italics):

"The estimated net present value differential of the 10% repayment rate versus the 20% repayment rate was deemed to be contingent consideration attributable to the Company's acquisition of the Libtayo (cemiplimab) rights described within the "Immuno-Oncology" section below; this portion is recorded as an increase to the Libtayo intangible asset over time as the Company repays such development costs to Sanofi."

- **Revise your disclosure accordingly.**

Response:

See applicable responses above.

***

If you have any questions regarding the foregoing, please contact me at (914) 847-7880.

Sincerely,

REGENERON PHARMACEUTICALS, INC.

/s/ Christopher Fenimore

Christopher Fenimore
Senior Vice President, Finance and
Chief Financial Officer