# REGENERON

August 1, 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: Frank 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 July 22, 2024, with respect to the above-referenced Annual Report on Form 10-K filed on February 5, 2024 (the "2023 Form 10-K"). Capitalized terms not otherwise defined in this letter have the respective meanings given to such terms in the Company's letter to the Staff dated May 20, 2024 (the "Prior Response").

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. We note your response to prior comment one and your intended disclosure revisions. As your disclosure of net product sales of Regeneron-discovered products appears to constitute a metric, the disclosure requirements set forth in Staff Release No. 33-10751 are applicable. Accordingly, please revise your future filings to include the information provided in your response that describes how management uses these operating metrics in managing or monitoring the performance of your business, and why these metrics provide useful information to investors.

#### Response:

In addition to the disclosure referenced in the Prior Response, we will include the following disclosure starting with the Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2024:

"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. We believe the information in the table is useful to investors as it demonstrates our pipeline productivity and our ability to innovate, discover, and develop new products, and bring those products to market either alone or based on contractual arrangements with other parties, which has a direct impact on our results of operations and financial condition. The table also shows the degree to which we, a collaborator, and/or a licensee is currently commercializing the products discovered by Regeneron. In addition, this information allows management and investors to assess the commercial trends and developments impacting Regeneron-discovered products. In arrangements where our collaborator or licensee is currently commercializing such products and is recording net product sales as a result, the net product sales shown in the table also are an important metric for management's review and assessment of (i) the revenues we record for our share of profits and/or royalties from such sales and (ii) the impact of our obligation to supply commercial product to certain of these collaborators or licensees."

#### **Notes to the Consolidated Financial Statements**

- 3. Collaboration, License and Other Agreements
- a. Sanofi, page F-17
- 2. We note your response to prior comment two. In order to illustrate the mechanics of your contingent reimbursement obligation and the amounts reported in your Statement of Operations, please provide us with the following:
- Provide us with the calculation of your contingent reimbursement obligation as of December 31, 2023 based on the cumulative development costs incurred prior to July 1, 2022 and the contractually specified reimbursement percentages, as well as a rollforward of your obligation for each period presented;

#### Response:

The calculation and rollforward of our contingent reimbursement obligation is as follows:

(In millions)	Contingent Reimbursement Obligation - Liability Recognized	Contingent Reimbursement Obligation - Liability Not Recognized		
Contingent reimbursement obligation as of December 31, 2021	\$	\$ 3,152		
Development costs incurred by the parties added to the contingent reimbursement obligation		98		
Development compensation payment (contractually defined as 10% of Regeneron's share of Antibody collaboration profits)	_	(110)		
Contingent reimbursement obligation as of July 1, 2022	\$ —	\$ 3,140		
One-time reduction to the contingent reimbursement obligation per terms of the amended Antibody License and Collaboration Agreement	_	(30)		
Development costs incurred by the parties added to the contingent reimbursement obligation <sup>(1)(3)</sup>	95	_		
Development compensation payment <sup>(2)(4)</sup>	(95)	(246)		
Contingent reimbursement obligation as of December 31, 2022	\$ —	\$ 2,864		
Development costs incurred by the parties added to the contingent reimbursement obligation <sup>(1)(3)</sup>	187	_		
Development compensation payment <sup>(2)(4)</sup>	(187)	(535)		
Contingent reimbursement obligation as of December 31, 2023	\$ —	\$ 2,329		

<sup>(1)</sup> As described in the Prior Response, as a result of the modification of the Sanofi Antibody collaboration (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).

<sup>&</sup>lt;sup>(2)</sup> Under the terms of the July 1, 2022 amendment to the Antibody License and Collaboration agreement, the development compensation payment in a given quarter is applied first towards development costs added to the contingent reimbursement obligation after the effective date of the amendment (i.e., the amounts included in (1) above) and any remaining amount of the development compensation payment in such quarter is then applied towards cumulative development costs added to the contingent reimbursement obligation prior to the effective date of the amendment. Subsequent to July 1, 2022, the development compensation payment (in the aggregate) is contractually defined as 20% of Regeneron's share of Antibody collaboration profits.

<sup>(3)</sup> See subsequent table - amount included in R&D expense.

<sup>(4)</sup> A portion of the development compensation payment for which a liability was not recognized was deemed to be contingent consideration attributable to the acquisition of the Libtayo rights and is recorded as an increase to the Libtayo intangible asset. Refer to the below response related to the Libtayo intangible asset for further details.

<sup>•</sup> Provide us with the calculation of "Regeneron's obligation for its share of Sanofi R&D expenses, net of reimbursement of R&D expenses" for each period presented;

#### Response:

The calculation of "Regeneron's obligation for its share of Sanofi R&D expenses, net of reimbursements of R&D expenses" for each period presented is as follows:

	Year Ended December 31,							
(In millions)	Statement of Operations Classification		2023		2022		2021	
Sanofi Antibody collaboration:								
Development costs incurred by the parties added to the contingent reimbursement obligation <sup>(1)</sup>	(R&D expense)	\$	(187)	\$	(95)	\$	_	
Regeneron's obligation for its share of Sanofi R&D expenses <sup>(2)</sup>	(R&D expense)		(38)		(42)		(47)	
Sanofi's reimbursement of Regeneron's R&D expenses <sup>(2)</sup>	Reduction of R&D expense		142		180		176	
Regeneron's obligation for its share of Sanofi R&D expenses, net of reimbursements of R&D expenses	Reduction of R&D expense/(R&D expense)	\$	(83)	\$	43	\$	129	

<sup>(1)</sup> See preceding table - amount added to the contingent reimbursement obligation in accordance with the contractually specified formula. As described in the Previous Response, such amount represents the research and development costs funded by Sanofi subsequent to July 1, 2022 (i.e., the increase to the contingent reimbursement obligation) that we are obligated to repay from our share of profits and for which we determined it was appropriate to recognize a liability.

<sup>&</sup>lt;sup>(2)</sup> Under the terms of the Antibody License and Collaboration Agreement, Sanofi is generally responsible for funding 80% to 100% of agreed-upon development costs. We record the reimbursable amounts from Sanofi as a reduction to R&D expense in the period in which such costs are incurred. When Sanofi performs research and development work, we also recognize, as research and development expense in the period when Sanofi incurs such expense, the portion of Sanofi's expenses that we are obligated to reimburse in accordance with the contractually specified formula, and which do not get added to the contingent reimbursement obligation per the terms of the contract.

<sup>•</sup> Quantify for us the estimated net present value differential of the 10% repayment rate versus the 20% repayment rate which was deemed to be contingent consideration attributable to your acquisition of the Libtayo rights and the amount recorded as an increase to the Libtayo intangible asset for each period presented.

## Response:

As described in the Prior Response, we concluded the modification to the Antibody LCA represented additional consideration transferred by the Company to Sanofi to acquire the exclusive worldwide rights to Libtayo. As of July 1, 2022, the estimated net present value differential of the 10% repayment rate versus the 20% repayment rate, which was deemed to be contingent consideration in an asset acquisition attributable to our acquisition of the Libtayo rights, was \$364 million.

Accordingly, a portion of the development compensation payment each quarter under the Antibody LCA is attributable to the acquisition of the Libtayo intangible asset, and as a result, such portion is recognized as an addition to the Libtayo intangible asset over time (i.e., each quarter). During the period from July 1, 2022 to December 31, 2022, \$25 million was recorded as an increase to the Libtayo intangible asset related to the differential of the 10% repayment rate versus the 20% repayment rate, and during the year ended December 31, 2023, \$73 million was recorded as an increase to the Libtayo intangible asset.

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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