

October 12, 2016

#### VIA EDGAR

Mr. Jim B. Rosenberg Senior Assistant Chief Accountant Office of HealthCare and Insurance U.S. Securities and Exchange Commission Division of Corporation Finance 100 F Street, NE Washington, D.C. 20549

# Re: Regeneron Pharmaceuticals, Inc. Form 10-K for the Fiscal Year Ended December 31, 2015 Filed February 11, 2016 File No. 000-19034

Dear Mr. Rosenberg:

This letter sets forth the responses of Regeneron Pharmaceuticals, Inc. (the "Company" or "Regeneron") to the comments of the staff (the "Staff") of the Securities and Exchange Commission (the "Commission") set forth in the Staff's letter dated September 28, 2016, with respect to the above-referenced Form 10-K. Capitalized terms not otherwise defined in this letter have the respective meanings given to such terms in the Company's letters to the Staff dated May 23, 2016, July 7, 2016, and August 19, 2016 (collectively, the "Prior Responses"). Set forth below in bold are the headings and text of the Staff's comments followed by the Company's response.

Notes to Consolidated Financial Statements 3. Collaboration Agreements a. Sanofi Immuno-Oncology, page F-16

**1**. Please refer to our prior comment one. As discussed in conference calls with you and other members of the company and its independent accounting firm on September 16th and 27th, we continue to have the following concerns:

- As to whether the Antibody and IO collaborations are in substance one arrangement, please tell us your consideration of the following as of the date of the IO in concluding that the collaborations are not in substance one arrangement:
  - Was the \$75 million reduction in funding in connection with the amended Antibody collaboration, which was based on the proportionate number of IO targets in the Antibody Collaboration to the total number of targets, representative of its economic

#### Response:

The Company believes that the \$75 million reduction in available funding in connection with the amended Antibody Collaboration was representative of its economic substance. The Company is being reimbursed for performing research and development services for actual expenses incurred and time incurred on a FTE basis, which is at market rates. The Company is not obligated to perform services beyond the available funding. This did not change for the targets/product candidates researched under the Antibody Collaboration when they were transferred to the IO Collaboration and, as a result, there was no change in economic substance. While there are additional funds available under the IO Discovery Agreement, the funds are fungible and the Company has no obligation to perform services beyond the total funding available. Additionally, the remaining available funding under the Antibody Collaboration is to reimburse the Company for actual costs and time incurred with no obligation to perform services beyond the remaining available funding. As described in the Company's letter to the Staff on August 19, 2016, the \$75 million reduction in available reimbursable research and development funding was proportionate with the number of total IO targets being pursued under the Antibody Discovery Agreement over the past several years relative to the total number of targets being researched under the Antibody Discovery Agreement over the same period (i.e., the reduction in funding was structured to be commensurate with the reduction in the Company's discovery activities to identify and validate potential drug discovery targets in the field of immuno-oncology and to develop fully human monoclonal antibodies against these targets as such activities are now performed as part of the IO Collaboration). Note that it is the Company's expectation that the cost to research a pre-clinical target/antibody product candidate should generally be the same and should not be impacted by whether the target/product candidate is an IO target/product candidate or not. In addition, the FTE rates that the Company charges Sanofi for research and development services performed are approximately the same under both the Antibody and IO Collaborations.

The methodology to quantify the amount of the reduction in funding was agreed to by both parties, as it was not practical to identify specific costs incurred associated with researching individual targets at such an early-stage of pre-clinical development.

The \$75 million was not related to any intangible assets (i.e., rights or intellectual property) as Sanofi already had such rights to the targets under the Antibody Collaboration, but rather related to the estimated research costs associated with the IO targets/product candidates.

• How would you assess the fair value of the IO targets transferred to the IO collaboration in relation to the Antibody agreement and your basis for the assessment?

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### Response:

• As described above, the \$75 million was related to reimbursement of anticipated research and development services, and not to any existing rights to intellectual property associated with the IO targets/product candidates transferred. The \$75 million represents fair value as

it is the estimated amount for what Sanofi pays the Company to perform research and development services based on actual third-party expenditures incurred and, for internal costs, incurred hours multiplied by an FTE rate (which, as described in the Prior Responses, is consistent with and within the range of prices the Company charges other collaborators for similar research and development services).

Additionally, given the early, pre-clinical stage of development (and the related future research, development, regulatory, and commercial risks), the Company estimates the fair value of the IO targets, or the early stage product candidates against such IO targets, that were transferred to the IO collaboration would be insignificant, both individually and in the aggregate, relative to the overall Antibody Collaboration (and therefore did not factor into the economic decisions of the parties outside of the \$75 million). In addition, it should be noted that Sanofi did not obtain any additional rights to the intellectual property relative to the IO targets/product candidates transferred from the Antibody Collaboration that would have increased the fair value of such targets/product candidates upon transfer, as Sanofi had already obtained rights under the Antibody Collaboration.

• In the negotiation of the IO and the amended Antibody collaborations, tell us about relevant discussions with Sanofi in connection with the transferred IO antibodies regarding their terms including the \$640 million upfront payment. How would you assess the transferred IO antibodies with respect to the \$640 million upfront payment and your basis for the assessment?

## Response:

- For the reasons described above, there were no discussions or negotiations with Sanofi in connection with the transferred IO targets/product candidates relative to the IO upfront payments of \$640 million (i.e., the \$640 million was negotiated irrespective of the transfer of IO targets/product candidates). The parties determined that \$75 million (as described above) was appropriate compensation for the reimbursable research and development services to be performed by the Company under the IO Collaboration in connection with the transferred IO targets/product candidates.
- How would you assess the potential for overlap/sharing of management, staff, facilities and/or information between the Antibody and IO collaborations to each of the collaborations and your basis for the assessment?

# Response:

• As with any of the Company's ongoing research projects (whether conducted under a Sanofi collaboration agreement, a collaboration agreement with a different third party, or developed independently by the Company), there is some level of overlap and sharing of management, staff, facilities, and other information. This, in and of itself, is not a presumptive, much less determinative, factor for concluding that two collaboration arrangements are interdependent of one another. Rather, this type of overlap and sharing is a function of the nature of the research and drug-development process and represents a matter of functional and administrative efficiency. Fundamentally, the research and development activities under the Antibody and IO Collaborations are not <u>interdependent</u> in terms of design, technology, or function. Each collaboration *could* stand on its own and

exist and function independently of the other collaboration. Notwithstanding that the Company has some level of personnel and facilities used to research and develop product candidates under both collaborations, it is <u>not</u> <u>necessary</u> for the success of either/both collaborations that such personnel/facilities be used for both. Furthermore, each of these collaborations could be terminated or expire without impacting the terms or activities conducted under the remaining collaboration; for example, the two collaboration agreements have different contractually stated expiration dates.

- With respect to the alternative accounting treatment, as provided in your response, and whether it complies with ASC 605-25, it is not clear why besides the mice, there is only one other unit of accounting. As discussed, it would appear that there would be at least two units of accounting besides the mice. Please provide us:
- an analysis of your determination of the units of accounting under ASC 605-25-25;

### Response:

 As noted in the Prior Responses, the Company concluded (and continues to believe) that the amendments to the Antibody Collaboration were not a material modification of the existing Antibody Discovery Agreement or Antibody License and Collaboration Agreement with Sanofi and that the IO Collaboration and the Antibody Collaboration should not be accounted for together as a single arrangement. However, the Company did consider what the accounting treatment would have been had the Company reached a conclusion that the IO Collaboration and the Antibody Collaboration should be accounted for together as a single new arrangement.

In the Company's letter to the Staff dated August 19, 2016, the Company noted that there would potentially be two units of accounting under the "alternative accounting treatment": (a) the deliverable associated with the mouse purchase agreement (the "mice"), and (b) the licenses to certain rights and intellectual property and research and development services under both the Antibody and IO Collaborations. The reason for that determination was that, in assessing what the "alternative accounting treatment" would be, the Company wanted to illustrate (a) the scenario that would yield the *largest* difference relative to the Company's current accounting treatment, and (b) an interrelationship of the collaborations and underlying deliverables that do not have standalone value and therefore would not be considered separate units of accounting.

An alternative answer (albeit one that was previously considered and rejected by the Company) could be that there were three units of accounting: (a) the mice ("mouse unit of accounting"), (b) the license to certain rights and intellectual property and research and development services under the Antibody Collaboration ("Antibody unit of accounting"), and (c) the license to certain rights and intellectual property and research and development services under the IO Collaboration ("IO unit of accounting"). The Company would recognize the reimbursements of capital improvements (for which Sanofi does not have separate utility) initially over the Antibody Collaboration performance period and then over the IO performance period from the date of the commencement of the IO Collaboration, as the IO unit of accounting will be amortized over a longer period than the Antibody unit of accounting.

The licensed intellectual property does not have standalone value separate from the research and development services (including manufacture of clinical supplies) under the respective collaboration primarily due to the fact that such rights were not sold separately by the Company, nor could Sanofi gain economic benefit from each license without fulfillment of other ongoing obligations by the Company, including the clinical supply arrangements. This conclusion is consistent with the accounting applied by the Company with respect to both the Antibody and IO Collaborations in its financial statements (please refer to the more detailed and related analysis of this point in the Company's letter to the Staff dated May 23, 2016).

 the amount of the total arrangement consideration and how it would be determined under ASC 605-25-30-1 including how any remaining deferred income under the Antibody collaboration before it was amended in connection with the IO collaboration would be considered;

# Response:

- Under the Company's current accounting treatment, the following arrangement consideration was recorded as deferred revenue upon receipt and was being amortized over the related performance period: (i) an \$85 million upfront payment received in 2007 in connection with the execution of the Antibody Discovery Agreement (\$32 million of which was remaining as deferred revenue as of July 2015), (ii) \$22 million of payments received from Sanofi in exchange for providing genetically modified mice (\$9 million of which was remaining as deferred revenue as of July 2015), (iii) \$30 million of reimbursements of capital expenditures received in connection with the Antibody Collaboration (\$16 million of which was remaining as deferred revenue as of July 2015), and (iv) the \$640 million of up-front payments received in connection with the execution of the IO Collaboration in July 2015. The arrangement consideration described in the preceding sentence was considered to be fixed and determinable as such amounts were contractually stated and non-refundable; the \$85 million, \$22 million, and \$30 million were fully paid to Regeneron prior to the July 2015 amendment of the Antibody Collaboration; and the \$640 million was fully paid to Regeneron shortly after execution of the IO Collaboration. As it relates to other arrangement consideration that the Company is entitled to under the Antibody and IO Collaborations, which was contingent upon entering the arrangements and which comprises reimbursement for ongoing research and development services and manufacture of clinical supplies, the Company records those reimbursable amounts as collaboration revenue proportionately as the Company incurs and recognizes the related expenses.
- how the total arrangement consideration would be allocated to the units of accounting including the selling prices that would be used and the basis used to determine selling prices under ASC 605-25-30-2,

### Response:

 Mouse unit of accounting - As it relates to the deliverable associated with the mouse purchase agreement, the Company would conclude that the mice (i.e., the deliverable) have value to Sanofi on a standalone basis. As noted in the Company's letter to the Staff dated August 19, 2016, there was objective evidence that the contractual value of \$22 million was the fair value of the mice at the time of execution of the original agreement since Regeneron had entered into agreements with other pharmaceutical companies with similar economic terms to the Sanofi agreement.

Antibody unit of accounting - The Company believes that the contractually stated Antibody up-front payment was representative of the best estimate of the standalone selling price of the license. In determining the amount of the up-front payment, the Company considered (a) amounts it had charged other third parties prior to execution of the Antibody Collaboration, including AstraZeneca and Astellas, for access to the Company's technology, (b) the specific rights transferred, (c) exclusivity provisions, (d) the length of the contract, and (e) costs incurred to research and develop targets, technologies, and antibody product candidates prior to execution of the Antibody Collaboration.

*IO unit of accounting* - The \$640 million consisted of \$265 million in connection with entering into the IO Discovery Agreement and \$375 million in connection with entering into the IO License and Collaboration Agreement. As noted in the Company's Prior Responses, under the terms of the IO License and Collaboration Agreement, the parties agreed to collaborate to co-develop the Company's antibody product candidate targeting the receptor known as programmed cell death protein 1, or PD-1 ("REGN2810"). At the time of execution of the IO License and Collaboration Agreement, REGN2810 was in Phase 1 clinical development by Regeneron.

The Company believes that the total contractually stated IO up-front payments are representative of the Company's best estimate of the standalone selling prices of the license granted. In determining best estimate of selling price, the Company considered prices charged by other companies for similar deals (i.e., license of rights to IO targets/product candidates), estimate of future development costs, exclusivity provisions, the competitive landscape, and the length of the contract. It should also be noted that the \$640 million did not in any way relate to the economics of the Antibody Collaboration, nor did it reflect the recovery of any economics under the prior Antibody Collaboration. Finally, as noted in the Company's Prior Responses, there was no discount provided to Sanofi related to the up-front payments.

• Since the contractual values of each of the units of accounting described in the bullet above approximate their estimated standalone selling prices, an allocation of the total arrangement consideration based on the relative standalone selling prices of each unit of accounting would yield the same amount as the contractual amounts. Therefore, the Company would have allocated (i) the contractual payments related to the mice (of which \$9 million remained as deferred revenue as of July 2015) to the mouse unit of accounting, (ii) the original \$85 million Antibody Collaboration up-front payment to the Antibody unit of accounting, (iii) the \$640 million of up-front payments received in connection with the execution of the IO Collaboration to the IO unit of accounting.

### how revenue for each deliverable would be recognized

#### Response:

• Under the "alternative accounting treatment", the Company would have recognized the remaining deferred revenue balance of \$9 million associated with the mouse unit of accounting as revenue in July 2015. As of July 2015, all of the mice under the August 2008 mouse purchase agreement had been delivered to Sanofi and all related payments had been received by the Company. The Company would have recognized the remaining deferred revenue balance associated with the Antibody unit of accounting over the estimated performance period (through 2020) related to the Antibody Collaboration. The Company would have recognized amounts related to the IO unit of accounting (i.e., IO up-front payments as well as the remaining deferred revenue balance associated with the reimbursements of capital expenditures) over the estimated performance period (through mid-2023), which is the longer of the contractual life of the arrangement or an estimate of the expected development period (for REGN2810).

• the amount of revenue that would have been recognized in 2015 and the six months ended June 30, 2016 and 2015.

## Response:

• See table below for a summary of the amount of revenue that the Company actually recognized compared to what would have recognized under the "alternative accounting treatment" (i.e., assuming three units of accounting as described above).

(in millions)	Six months ended June 30, 2015	Six months endedYear endedJune 30, 2015December 31, 2015		Six months ended June 30, 2016	
Actual revenue recognized	\$ 5.	2 \$	50.3	\$	45.1
Revenue that would have been recognized under "alternative					
accounting treatment"	5.2(*	") \$	57.8	\$	43.9
Difference	_	- \$	7.5	\$	(1.2)

\* - The IO Collaboration was not executed until July 2015; therefore, there would have been no change to the Company's accounting as of June 2015.

• Your analysis demonstrating that the alternative accounting would not be materially different than the accounting applied in your financial statements for 2015, the six months ended June 30, 2016 and future periods.

### Response:

• The Company reported pre-tax income of \$1.225 billion for the year ended December 31, 2015 and \$622 million for the six months ended June 30, 2016. Therefore, the differences (as described in the section above) in the alternative accounting and the accounting applied in the Company's historical financial statements do not represent material differences on a pre- or post-tax basis (e.g., such differences represent a less than a 1% impact on the Company's pre-tax income for each of those periods). In addition, the differences in future periods would also not be material (maximum difference in revenue of approximately \$2.5 million in any year from 2016 forward under the Company's current amortization methodology compared to the "alternative accounting treatment" assuming three units of accounting).

In addition, the difference in deferred revenue under the "alternative accounting treatment" compared to the accounting applied in the Company's financial statements would also not be materially different for the year ended December 31, 2015 (\$7.5 million difference), six months ended June 30, 2016 (\$6.3 million difference), or any future period (maximum difference in deferred revenue of approximately \$5.0 million in any year from 2016 forward). By way of context, the Company reported a total of \$818 million in deferred revenue as of December 31, 2015.

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If you have any questions regarding the foregoing, please contact me at (914) 847-7270.

Very truly yours,

REGENERON PHARMACEUTICALS, INC.

/s/ Robert E. Landry

Robert E. Landry Senior Vice President, Finance and Chief Financial Officer

cc: Bonnie Baynes, Staff Accountant