

May 23, 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 Form 8-K dated February 9, 2016 Filed February 9, 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 May 2, 2016, with respect to the above-referenced Form 10-K and Form 8-K (collectively, the "Filings"). Set forth below are the headings and text of the Staff's comments followed by the Company's response.

#### Form 10-K for the Year Ended December 31, 2015

#### Patents, Trademarks, and Trade Secrets, page 22

1. We refer to the third paragraph under the heading which discloses that the patents for your three commercially marketed products and ZALTRAP "generally" expire between 2020 and 2029 and "may be subject" to extension. Please confirm that you will revise future filings to discuss separately the patent coverage for each product that is material to your business, including the patent expiration dates for any material patents and the current status of efforts to extend those expiration dates. Also, discuss coverage by jurisdiction where material. With reference to your disclosures in the fourth paragraph under the heading, please also confirm that in future filings you will revise your discussion of material licenses to discuss the term of those licenses. To the extent that the term of a material license is tied to patent expiration, please confirm that you will identify the applicable expiration date in the future filing.

## Response:

In its future Form 10-K filings, the Company will include disclosure relating to patent coverage for each product that the Company considers material to its business at the time of filing, including (i) patent expiration dates for patents viewed as material by the Company, (ii) the current status of relevant efforts to extend those expiration dates, if applicable, and (iii) patent coverage by jurisdiction, to the extent considered material by the Company.

In its future Form 10-K filings, the Company also will include the term of any licenses it considers material to its business at the time of filing and, to the extent any such license is tied to patent expiration, the applicable expiration date. By way of background, the Company did previously disclose in the "Liquidity and Capital Resources - *License and Settlement Agreements with Genentech*" section of its Form 10-K for the fiscal year ended December 31, 2015 that the royalty payments to Genentech based on sales of EYLEA<sup>®</sup> (aflibercept) Injection (which the Company was obligated to pay pursuant to the agreements discussed in the fourth paragraph under "Patents, Trademarks, and Trade Secrets" referenced in this comment) ended on May 7, 2016, as expressly set forth in the agreements.

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

## **<u>1. Business Overview and Summary of Significant Accounting Policies</u>** <u>Accounts Receivable - Trade, page F-10</u>

2. Please tell us why your days sales outstanding for the quarter ended March 31, 2014 of 199 days is substantially higher than for the quarter ended March 31, 2015 of 168 days. Further tell us why the days sales outstanding for each of these quarters is substantially higher than for the quarters for the rest of the respective fiscal year. In this regard, we computed days sales by dividing accounts receivable - trade, net as end of a quarter by net product sales for the respective quarter and multiplying the result by the number of days in the quarter.

#### Response:

As disclosed in the "Liquidity and Capital Resources - *Sources and Uses of Cash*" section of the Company's Form 10-Q for the quarter ended March 31, 2014, the Company originally offered extended payment terms to its EYLEA customers in connection with the U.S. product launch of EYLEA in the fourth quarter of 2011 and subsequently shortened, effective January 2014, the payments terms to certain of its EYLEA customers. The Company had initially offered extended payment terms in recognition of anticipated delays in reimbursement to physicians by government and commercial payers during the launch of EYLEA.

The Company commenced sales of EYLEA in the United States for the treatment of diabetic macular edema ("DME") in the third quarter of 2014 and macular edema following branch retinal vein occlusion ("BRVO") in the fourth quarter of 2014. In recognition of anticipated delays in reimbursement to physicians by government and commercial payers during the initial launch of EYLEA for these new indications, the Company lengthened its payment terms to its distributors for approximately 5 months effective August 2014 (with the understanding that such payment terms would revert back to the January 2014 payment terms in February 2015). As disclosed in the "Liquidity and Capital Resources - *Sources and Uses of Cash*" section of the Company's Form 10-Q for the quarter ended March 31, 2015, "As of March 31, 2015, Sanofi, Bayer HealthCare, and trade accounts receivable increased by \$321.1 million, compared to December 31, 2014, primarily due to higher trade accounts receivable resulting from lengthened payment terms to certain of our U.S. EYLEA customers effective mid-2014." Note that EYLEA sales in the United States to these U.S. EYLEA customers (i.e., the Company's distributors) account for a significant portion of the Company's net product sales.

A change in payment terms offered to distributors does not have an impact on the Company's days sales outstanding ("DSO") in the period in which the change in payment terms was made effective, but rather in subsequent periods when accounts receivable amounts in respect of sales made under the revised payment terms are due to be collected. As an example, the shortening of payment terms effective in January 2014 resulted in a lower DSO beginning in the second quarter of 2014, in contrast to the first quarter of 2014 and periods prior. Additionally, the lengthening of payment terms effective in August 2014 resulted in an increase in the Company's DSO commencing in the first quarter of 2015, in contrast to the second, third, and fourth quarters of 2014.

The Company monitors product supply levels in the distribution channel, as well as sales by its customers of EYLEA to healthcare providers. As noted in the Company's quarterly earnings releases for the periods ended March 31, 2014 through March 31, 2015 furnished as exhibits to the Company's Current Reports on Form 8-K, overall EYLEA distributor inventory levels were consistently within the Company's one- to two- week targeted range from the first quarter of 2014 through the first quarter of 2015. In addition, during 2015, 2014, and 2013, the Company did not recognize any charges for write-offs of accounts receivable related to its marketed products, as disclosed in Item 7A. "Quantitative and Qualitative Disclosures About Market Risk - Credit Quality Risk" of the Company's Form 10-K for the fiscal year ended December 31, 2015.

## 3. Collaboration Agreements a. Sanofi Immuno-Oncology, page F-16

3. Please provide us a full accounting analysis of the July 2015 IO Collaboration with Sanofi and, as amended in connection with the IO Collaboration, the Antibody Discovery Agreement and its License and Collaboration Agreement with Sanofi. Include in your analysis:

- How you viewed the IO Collaboration and the amended agreements (i.e. separately or together) and the basis for your conclusion;
- Evaluation of the deliverables;
- Arrangement consideration, its determination and allocation;
- Revenue and expense recognition; and
- Authoritative literature supporting your analysis.

### Response:

## Background

In November 2007, the Company entered into a global, strategic collaboration with Sanofi to discover, develop, and commercialize fully human monoclonal antibodies (the "Antibody Collaboration"). The Antibody Collaboration is governed by the companies' Discovery and Preclinical Development Agreement (the "Antibody Discovery Agreement") and a License and Collaboration Agreement (each as amended). In July 2015, the Company and Sanofi entered into a global strategic collaboration to discover, develop, and commercialize antibody-based cancer treatments in the field of immuno-oncology (the "IO Collaboration"). The Company's discovery activities to identify and validate potential drug discovery targets in the field of immuno-oncology and develop fully human monoclonal antibodies against these targets will be funded by Sanofi under the terms of the IO collaboration, as further described below.

The IO Collaboration is governed by an Immuno-oncology Discovery and Development Agreement (the "IO Discovery Agreement"), and an Immuno-oncology License and Collaboration Agreement (the "IO License and Collaboration Agreement"). In connection with entering into the IO Discovery Agreement, Sanofi made a \$265.0 million non-refundable up-front payment to the Company. Pursuant to the IO Discovery Agreement, the Company will incur costs to identify and validate potential immuno-oncology targets and develop therapeutic antibodies against such targets through clinical proof-of-concept. Sanofi will reimburse the Company for up to \$825.0 million (the "IO Discovery Funding") of these costs, subject to certain annual limits, which consists of (i) \$750 million in new funding and (ii) \$75 million of funding that would have otherwise been available to Regeneron under the existing Antibody Discovery Agreement with Sanofi. The Company will reimburse Sanofi for half of the development costs they funded that are attributable to clinical development of antibody product candidates under the IO Discovery Agreement from Regeneron's share of future profits, if any, to the extent they are sufficient for this purpose. However, the Company is not required to apply more than 10% of its share of the profits from IO Collaboration products in any calendar quarter towards reimbursing Sanofi for these development costs. With regard to product candidates for which proof-of-concept is established, Sanofi will have the option to license rights to the candidate pursuant to the IO License and Collaboration Agreement (as further described below). If Sanofi does not exercise its option to license rights to a product candidate, the Company will retain the exclusive right to develop and commercialize such product candidate and Sanofi will be entitled to receive a royalty on sales.

In connection with entering into the IO License and Collaboration Agreement, Sanofi made a \$375.0 million non-refundable upfront payment to the Company. If Sanofi exercises its option to license rights to a product candidate thereunder, it will co-develop the drug candidate with the Company through product approval. Principal control of development of each product candidate that enters development under the IO License and Collaboration Agreement will alternate between the Company and Sanofi on a candidate-by-candidate basis. Sanofi will fund drug candidate development costs up front (i.e., Sanofi will "pay as they go") for the candidates for which it is the principal controlling party and the Company will reimburse half of the total development costs for all such candidates from its share of future profits, if any, to the extent they are sufficient for this purpose, subject to the same 10% reimbursement limitation described above. In addition, Sanofi and the Company will share equally, on an ongoing basis, the development costs for the drug candidates for which the Company is the principal controlling party. The party having principal control over the development of a product candidate will also lead the commercialization activities for such product candidate in the United States. For all products commercialized under the IO License and Collaboration Agreement, Sanofi will lead commercialization

activities outside of the United States. Each party will have the right to co-promote licensed products in countries where it is not the lead commercialization party. The parties will share equally in any profits from worldwide sales of collaboration products. Regeneron is obligated to use commercially reasonable efforts to supply clinical requirements of each drug candidate under the IO License and Collaboration Agreement until commercial supplies of that IO drug candidate are being manufactured. Prior to commencement of manufacturing commercial supplies, both parties will determine who will be responsible for manufacturing and finishing commercial supplies for each IO licensed product.

Under the terms of the IO License and Collaboration Agreement, the parties will also co-develop the Company's antibody product candidate targeting the receptor known as programmed cell death protein 1, or PD-1 ("REGN2810"). The parties will share equally, on an ongoing basis, development expenses for REGN2810 up to a total of \$650.0 million (for clarity, Regeneron would have to solely fund any development expenses in excess of such amount). The Company will have principal control over the development of REGN2810 and will lead commercialization activities in the United States, subject to Sanofi's right to co-promote, while Sanofi will lead commercialization activities of the United States and the parties will equally share profits from worldwide sales. The Company will be entitled to a milestone payment of \$375.0 million in the event that sales of all licensed products targeting PD-1 (including REGN2810), together with sales of any other products licensed under the IO License and Collaboration Agreement and sold for use in combination with a licensed product targeting PD-1, equal or exceed \$2.0 billion in any consecutive twelve-month period. At the time of execution of the IO License and Collaboration Agreement at the time of execution of such contract.

## Analysis of the IO Collaboration and amendments to the Antibody Collaboration

The Company first determined whether (a) the Antibody Discovery Agreement and Antibody License and Collaboration Agreement had been "materially modified" and (b) the IO Collaboration and the Antibody Collaboration should be accounted for together. The Company does not deem the amendments to the Antibody Collaboration to be a material modification of the existing Antibody Discovery Agreement or Antibody License and Collaboration Agreement with Sanofi, and concluded that the IO Collaboration and the Antibody Collaboration should not be accounted for together, primarily in light of the following factors:

- Sanofi previously agreed to fund up to \$75 million for 2008, \$100 million for 2009, and \$160 million per year from 2010 2017 (or a total of approximately \$1.4 billion) in connection with the Antibody Discovery Agreement. The reductions in funding pursuant to the amended Antibody Discovery Agreement from \$160 million in each of 2015, 2016, and 2017 to \$145 million, \$130 million, and \$130 million, respectively, were not considered to be a significant modification relative to Sanofi's overall funding obligations under the Antibody Discovery Agreement.
- The \$75 million of aggregate funding from the Antibody Collaboration, as described above, used to reimburse the Company for a portion of its IO Discovery program costs is not material to the total anticipated funding under the IO Collaboration.
- Although IO product candidates and products will no longer be within the scope of the Antibody Collaboration, the broad deliverables under the agreements governing the Antibody Collaboration have not changed i.e., the Company will still be identifying and developing targets, providing research and development and manufacturing services, etc., as originally required.

- There were no other amendments to the economics of, or substantive changes to, the original Antibody Collaboration.
- There is no pricing interdependency between the new deliverables under the IO Collaboration agreements and the deliverables under the Antibody Collaboration agreements.
- There were no discounts provided to Sanofi in the new IO Collaboration agreements that would indicate that the new agreements were somehow linked to the economics of the existing Antibody Collaboration agreements.

Therefore, the Company concluded that IO Collaboration agreements should be considered "new" agreements and did not modify its accounting for the Sanofi Antibody Collaboration.

## Evaluation of deliverables under the IO Collaboration

In accordance with ASC 605-25, *Multiple-element arrangements*, arrangement consideration shall be allocated at the inception of the arrangement to all relevant (i.e., non-contingent) deliverables. In making this assessment, the Company considered which payments are fixed or determinable at the inception of the arrangement and which are contingent. Deliverables associated with the IO Collaboration are as follows:

(i) License to certain rights and intellectual property: See discussion under "*Accounting for the IO Collaboration up-front payments*" below.

(ii) Providing research and development services:

As noted above, under the IO Collaboration, Sanofi reimburses the Company for certain costs in connection with researching and developing product candidates. The following accounting guidance was utilized in determining the appropriate accounting for such payments:

- ASC 808-10-45-3: "Payments between participants pursuant to a collaborative arrangement that are within the scope of other authoritative accounting literature on income statement classification shall be accounted for using the relevant provisions of that literature. If the payments are not within the scope of other authoritative accounting literature, the income statement classification for the payments 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."
- ASC 808-10-45-4: "An entity shall evaluate the income statement classification of payments between participants pursuant to a collaborative arrangement based on the nature of the arrangement, the nature of its business operations, the contractual terms of the arrangement, and whether those payments are within the scope of other authoritative accounting literature on income statement classification. If the payments are within the scope of other authoritative accounting literature, then the entity shall apply the relevant provisions of that literature."
- ASC 730-20, *Research and Development Arrangements*, which provides guidance on accounting for research and development arrangements when another company funds research and development costs, and requires a company to determine the nature of the obligation it incurs when it enters into a research and development funding arrangement to ascertain whether the obligation is a liability to repay the funding party or to perform contractual services. ASC 730-20-25-3 provides that, "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." ASC 730-20-25-4 further provides that, "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."

As described in the "Background" section above, the Company and Sanofi are each active participants in the collaborations' activities, and both parties are exposed to significant risks and rewards dependent on the commercial success of the activity (e.g., profit sharing, sales milestones, etc.). Therefore, the Company deemed the arrangement to be a collaboration and Sanofi to be the Company's customer under the arrangement. Note that the Company provides similar research and development services to Sanofi under the Antibody Collaboration and treats Sanofi as its "customer" under such arrangement. None of the payments Sanofi makes to the Company under the IO Collaboration are refundable if research efforts do not yield targets that can be clinically tested, receive regulatory approval, and generate profits upon commercialization. Pursuant to the IO Discovery Agreement, the Company will reimburse Sanofi for half of the development costs Sanofi funded that are attributable to clinical development of IO product candidates from Regeneron's share of future profits to the extent they are sufficient for this purpose. Pursuant to the IO License and Collaboration Agreement, Sanofi will fund drug candidate development costs up front for the candidates for which it is the principal controlling party and the Company will reimburse half of the total development costs for all such candidates from its share of future profits to the extent they are sufficient for this purpose. In addition, the Company is not required to apply more than 10% of its share of the profits from IO Collaboration products in any calendar quarter towards reimbursing Sanofi for these development costs. Given that Regeneron's reimbursement obligation for half of certain development costs funded by Sanofi is contingent upon (a) regulatory approval of an IO product, which is beyond the Company's control, and (b) the IO product(s) becoming profitable (i.e., generating more revenue than commercialization-related costs and cost of goods sold), the Company concluded that there had been a substantive and genuine transfer of risk (i.e., it was not probable at that point in time that any or all of the Company's contingent reimbursement obligation would be repaid by Regeneron). Therefore, the funding from Sanofi was fully at risk and accordingly the Company was not required to record a liability related to any potential development balance repayment. Consistent with the Company's accounting treatment for other similar collaboration arrangements, the Company records its internal and third-party development costs associated with the agreements as research and development expenses; and, where the Company is entitled to reimbursement of a portion of the research and development expenses that it incurs, the Company records those reimbursable amounts as collaboration revenue proportionately as the Company recognizes its related expenses. In addition, in periods when Sanofi incurs certain development expenses, the Company also recognizes, as additional research and development expense, the portion of its collaborators' development expenses that it is obligated to reimburse.

## (iii) Manufacturing clinical supplies:

The Company has an obligation to provide clinical supply manufacturing services. The price charged to Sanofi for manufacturing clinical supplies is at the fully burdened manufacturing cost, as defined in the agreement. Furthermore, Sanofi is obligated to reimburse the Company for the cost of any failed lots. Therefore, the Company records any reimbursable amounts as collaboration revenue proportionately as it recognizes its related clinical supply manufacturing expenses.

# (iv) Other deliverables:

With regard to Sanofi's option to license rights to product candidates for which proof-of-concept has been established ("opt-in" right), the Company considers that right to be a contingent deliverable at the inception of the arrangement. This conclusion is primarily based on the following factors:

- Sanofi's opt-in decision is contingent upon certain future events (i.e., results of clinical trials) that are not within Sanofi's control;
- Sanofi has no obligation to opt-in (i.e., it has sole discretion as to whether it will exercise its opt-in right), regardless of the results from Regeneron's proof-of-concept clinical trials; and
- The decision to exercise Sanofi's opt-in right is a separate economic purchasing decision if Sanofi decides to opt-in, it will be required to reimburse the Company for half of certain of the Company's development expenses under the IO License and Collaboration Agreement as noted above; therefore, the opt-in right was not granted to Sanofi at a significant incremental discount.

Therefore, the Company excluded this contingent deliverable from the initial allocation of the up-front payment.

Finally, a joint steering committee ("JSC") comprised of an equal number of representatives from each of Sanofi and the Company has been established and is responsible for, among other things, reviewing and approving the overall development program. With regard to its JSC participation, the Company did not account for this as a deliverable separately as (a) it does not have standalone value from the research and development services being provided and (b) any services deemed to be provided under this deliverable would not be considered material given that the JSC meets quarterly and only requires participation of three Company representatives.

# Accounting for the IO Collaboration up-front payments

According to ASC 605-25-25-3, "separate contracts with the same entity or related parties that are entered into at or near the same time are presumed to have been negotiated as a package and shall, therefore, be evaluated as a single arrangement in considering whether there are one or more units of accounting...." Given that both the IO Discovery Agreement and IO License and Collaboration Agreement were (i) negotiated and executed at the same time, and (ii) REGN2810, which was in Phase 1 clinical development at the time that the IO Collaboration was entered into and had not reached proof-of-concept, was included as part of the IO License and Collaboration Agreement even though that agreement broadly covers product candidates for which proof-of-concept has already been established, the Company combined the two up-front payments into an aggregate amount of \$640 million and accounted for such aggregate amount accordingly.

In order to determine the appropriate accounting for the \$640 million, the Company considered whether the license to Regeneron's intellectual property, which is a deliverable provided to Sanofi in exchange for the up-front payments, should be considered a separate unit of accounting. Based on an evaluation of the information below, the Company concluded that the license did not have standalone value, and, therefore, the deliverables were considered a single unit of accounting.

## In accordance with ASC 605-25-25-5,

"the delivered item or items shall be considered a separate unit of accounting if both of the following criteria are met:

- a) The delivered item or items have value to the customer on a standalone basis. The item or items have value on a standalone basis if they are sold separately by any vendor or the customer could resell the delivered item(s) on a standalone basis. In the context of a customer's ability to resell the delivered item(s), this criterion does not require the existence of an observable market for the deliverable(s); and
- b) If the arrangement includes a general right of return relative to the delivered item, delivery or performance of the undelivered item or items is considered probable and substantially in the control of the vendor."

Since there is no right of return relative to the up-front payments (criterion "b" above), the Company considered the following factors in determining whether the delivered item that Sanofi received in exchange for the up-front payments (i.e., license to certain intellectual property) has value to Sanofi on a standalone basis:

- Regeneron is responsible for manufacturing and providing clinical supplies to Sanofi. Pursuant to the IO Discovery Agreement, "Regeneron shall supply Formulated Bulk Product and Finished Product for Clinical Supply Requirements"; and, pursuant to the IO License and Collaboration Agreement, "Regeneron will use Commercially Reasonable Efforts to provide an adequate and timely supply of Formulated Bulk Product for Clinical Supply Requirements of IO Licensed Products in the Field in the Territory in accordance with the Manufacturing Plan. Regeneron may use its Manufacturing facilities or, subject to Sanofi's prior written approval, such approval not to be unreasonably withheld, conditioned or delayed, Sanofi or Third Parties to Manufacture such Formulated Bulk Product." Accordingly:
  - It is within the Company's control and discretion whether to have Sanofi or another third party manufacture clinical supplies of IO licensed products if Regeneron opts not to manufacture such supplies;
  - The Company has the technical capabilities, know-how, and expertise, as well as the "cell banks," to be able to manufacture clinical supplies of these IO product candidates; and
  - The Company does not have a history of outsourcing any manufacturing of clinical supplies.
- The Company is responsible for providing research and development services to Sanofi. The objective of the research and development services is to develop IO antibody product candidate(s) utilizing the Company's proprietary technology and expertise. The ultimate objective is to receive regulatory approval of the product(s) developed.
  - The Company will receive reimbursement from Sanofi for a portion of the research development costs it incurs (as described above).
  - As it relates to research and development services performed by the Company under the IO Discovery Agreement, the Company has an ability to discover and identify targets using its unique know-how and technology.
  - As it relates to research and development services performed by the Company under the IO License and Collaboration Agreement, the fees charged to Sanofi for the research and development services (i.e., FTE rate) are consistent with and within the range of prices the Company charges Sanofi and other collaborators for similar research and development services provided under other collaboration arrangements.

- The Company has principal control over the development and commercialization of REGN2810.
- Under section 4.4 of the IO License and Collaboration Agreement, Sanofi only has the right to sublicense the products subject to the IO Collaboration with prior written consent from the Company (consent may not be unreasonably withheld with respect to rights outside the Major Market Countries and may be withheld for any reason in Major Market Countries).

At the inception of the IO Collaboration, the Company's significant deliverables consisted of (i) license to certain rights and intellectual property, (ii) providing research and development services, and (iii) manufacturing clinical supplies. Based on an evaluation of the information above, the Company concluded that the license to the intellectual property does not have standalone value primarily due to the fact that such rights were not sold separately by the Company, nor could Sanofi gain economic benefit from the license without fulfillment of other ongoing obligations by the Company, including the clinical supply arrangement. Therefore, the deliverables were considered a single unit of accounting. Consequently, the total of the up-front payments of \$640 million was recorded as deferred revenue upon receipt and is recognized as collaboration revenue over the period for which the Company is obligated to perform research and development activities for Sanofi ("performance period") - the longer of the contractual life of the arrangement or an estimate of the expected development period (for REGN2810). The Company will periodically review and, if necessary, revise the estimated performance period prospectively.

## <u>11. Debt</u> <u>a. Convertible Debt</u> <u>Warrant Transactions, page F-32</u>

4. Please tell us why the amendment entered into in November 2015 was not accounted for similar to the amendment entered into in November 2014 whereby you accounted for warrants as a liability effective with the amendment and subsequently measured them at fair value with changes in fair value recognized in earnings.

## Response:

The November 2014 amendment agreement with a warrant holder differed in certain material respects from the November 2015 amendment agreement with a warrant holder, and thus was accounted for differently.

Under the November 2014 amendment agreement with a warrant holder (Goldman, Sachs & Co., or "GS"), the parties agreed to reduce a portion of the number of warrants held by GS by up to a maximum of 493,229, for an aggregate amount payable by the Company not to exceed \$148.5 million. The reduction in the number of warrants was determined based on the number of warrants with respect to which GS had closed out its hedge position, provided that GS did not effect any purchases at a price per share exceeding \$397.75 per share, during the period starting on November 26, 2014 and ending no later than February 12, 2015. The Company was obligated to settle any payments due under this amendment agreement, in cash, in February 2015.

The Company evaluated whether the November 2014 amendment agreement should be accounted for as an equity instrument or liability upon execution of the agreement, and considered the following guidance from ASC 480, *Distinguishing liabilities from equity*:

- ASC 480-10-25-8: "An entity shall classify as a liability (or an asset in some circumstances) any financial instrument, other than an outstanding share, that, at inception, has both of the following characteristics:
  - a. It embodies an obligation to repurchase the issuer's equity shares, or is indexed to such an obligation.
  - b. It requires or may require the issuer to settle the obligation by transferring assets."
- ASC 480-10-55-30: "Consider, for example, a puttable warrant that allows the holder to purchase a fixed number of the issuer's shares at a fixed price that also is puttable by the holder at a specified date for a fixed monetary amount that the holder could require the issuer to pay in cash. The warrant is not an outstanding share and therefore does not meet the exception for outstanding shares in paragraphs 480-10-25-8 through 25-12. As a result, the example puttable warrant is a liability under those paragraphs, because it embodies an obligation indexed to an obligation to repurchase the issuer's shares and may require a transfer of assets. It is a liability even if the repurchase feature is conditional on a defined contingency in addition to the level of the issuer's share price."

Given that the November 2014 amendment agreement contained a conditional obligation of the Company that required settlement in cash, and the Company's obligation was effectively indexed to the Company's share price through the warrant reduction formula described above, the Company concluded that the November 2014 amendment agreement should be accounted for as a liability.

Under the November 2015 amendment agreement with another warrant holder (Credit Suisse Capital LLC, or "CS"), the parties agreed to reduce a portion of the number of warrants held by CS by up to a maximum of 476,376. The reduction in the number of warrants was determined based on the number of warrants with respect to which CS closed out its hedge position, provided that CS did not effect any purchases at a price per share exceeding \$535.00 per share, during the period starting on November 16, 2015 and ending no later than February 9, 2016. In contrast to the amendment agreement with GS described above, pursuant to the amendment agreement with CS, the Company was able to settle, <u>at its option</u>, any payments due under the amendment agreement in cash <u>or</u> by delivering shares of the Company's common stock. In addition, the November 2015 amendment agreement provided that the Company had sufficient authorized and unissued shares if share-settled. Therefore, the instrument did not meet the criteria for liability accounting under the guidance cited above, and equity classification was deemed appropriate. As a result, any payments made under the November 2015 amendment agreement were recorded to additional paid-in capital, consistent with the original accounting for the warrants in 2011. Disclosure has been provided in the Company's Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2016 to provide context for the accounting treatment for the November 2015 amendment agreement agreement as follows: "The Company may settle, at its option, any payments due under the amendment agreement in cash or by delivering shares of Common Stock."

## <u>Form 8-K filed February 9, 2016</u> <u>Exhibit 99.1</u> Table 3

5. Please refer to your non-GAAP net income and related per share amounts. Explain to us precisely what the non-cash income tax adjustment represents and the components included

therein. Also explain to us what non-GAAP income taxes represent after the non-cash income tax adjustment is deducted from GAAP income tax expense. In this regard, it appears that not only do you exclude certain elements of income tax expense in arriving at non-GAAP net income, but it also appear that you fail to recognize additional tax for the increase in pre-tax non-GAAP income. As such, it does not appear that your non-GAAP net income reflects the full income tax consequences of your pre-tax non-GAAP income. If that is the case, tell us what your non-GAAP net income would have been for each of the last three fiscal years had you included the full income tax consequences of your pre-tax non-GAAP income.

#### Response:

The Company has described what its non-GAAP adjustments represent in its quarterly earnings releases furnished as exhibits to the Company's Current Reports on Form 8-K. As noted in the earnings release furnished as an exhibit to the Company's Current Report on Form 8-K filed February 9, 2016, "As there was a significant difference between the Company's effective tax rate, which is utilized for calculating GAAP income tax expense, and actual cash income taxes paid or payable, GAAP income tax expense is not deemed useful in evaluating the Company's operating performance." The Company believes that the presentation of the tax measure utilized in its reconciliation of GAAP net income to non-GAAP net income is relevant and useful to analysts and investors, and helps those parties to better understand the Company's operating performance. The Company also provides financial guidance to investors on this basis. In addition, management utilizes this non-GAAP measure for planning, forecasting, assessing historical performance, and making financial and operational decisions. Note that the Company does not currently have any of its incentive compensation plans directly tied to non-GAAP financial results.

For 2015, the Company's non-cash income tax adjustment represents an adjustment from GAAP income tax expense to the amount of taxes that are paid or payable in cash in respect of the current period. For 2014 and 2013, income tax expense was excluded from the Company's non-GAAP net income, as GAAP income tax expense was principally a non-cash expense (i.e., the Company did not pay a significant amount of cash taxes). For 2015, 2014, and 2013, the non-GAAP income tax adjustment reduced GAAP income tax expense by utilizing net operating loss and tax credit carryforwards, as well as tax deductions ("excess tax benefits") in connection with employee exercises of stock options that are recorded to additional paid-in capital pursuant to ASC 718-20. The fact that the Company had unused federal and state net operating loss carryforwards related to employee exercises of stock options was disclosed in the Company's prior Form 10-K filings.

Further, it should be noted that in determining the non-cash tax adjustment, the Company did consider the non-cash tax consequences of its non-GAAP pre-tax adjustments. For example, in the Company's Current Report on Form 8-K (filed February 11, 2014) that included as an exhibit the earnings release reporting its financial results for the fiscal year ended December 31, 2013, the Company presented an income tax adjustment of \$289 million, which represented the GAAP income tax provision the Company had recorded in its 2013 operating results. As noted above, during 2013, GAAP income tax expense was principally a non-cash expense. The Company considered the income tax consequences of the Company's pre-tax non-GAAP adjustments, or \$80 million, which was calculated as the sum of the pre-tax non-GAAP adjustments multiplied by the Company's statutory tax rate. However, given that income taxes were primarily a non-cash expense in 2013, and that the \$80 million would not have resulted in any additional cash taxes paid or payable, the Company chose not to present the \$80 million adjustment separately in its reconciliation of GAAP net income to non-GAAP net income. The \$80 million adjustment would not result in any additional cash taxes paid or payable since (i) the cash tax impact of

the share-based compensation is not deductible at the time the share-based compensation expense is recorded by the Company, but a deduction for tax purposes occurs when the employee exercises their stock options, and (ii) the cash tax impact of the pre-tax adjustments related to convertible note transactions was offset by the utilization of net operating loss and tax credit carryforwards, as well as excess tax benefits in connection with employee exercises of stock options. In other words, had the Company separately presented the \$80 million non-GAAP tax expense associated with tax effecting the non-GAAP pre-tax adjustments, it would have also increased the "income tax adjustment" line to \$369 million, resulting in the same net result (\$289 million) that the Company presented. The same rationale was applied in preparation of the Company's 2014 reconciliation of GAAP net income to non-GAAP net income included in its quarterly earnings release furnished as an exhibit to the Company's Current Report on Form 8-K.

In 2015, when determining the amount of the non-cash income tax adjustment, the Company again considered the cash tax impact of the pre-tax non-GAAP income reconciling items. In other words, as described above, there was no cash tax impact related to the pre-tax non-cash share-based compensation expense adjustments. Therefore, if the Company had presented the income adjustment associated with the non-cash share-based compensation expense (the statutory rate multiplied by the sum of the non-cash share-based compensation expense adjustments), this would have resulted in approximately \$165 million of additional tax expense; however, since there was no cash impact of this additional tax expense, the Company would have also added an additional \$165 million to its non-cash tax adjustment line, leading to the same net result.

The Company's presentation of the tax adjustment was provided in a manner that the Company determined was most meaningful and useful to analysts, investors, and management.

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As requested by the Staff, the Company acknowledges that:

- The Company is responsible for the adequacy and accuracy of the disclosure in the Filings;
- Staff comments or changes to disclosure in response to Staff comments do not foreclose the Commission from taking any action with respect to the Filings; and
- It is the Staff's view that the Company may not assert Staff comments as a defense in any proceeding initiated by the Commission or any person under the federal securities laws of the United States.

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 Dorman Yale, Staff Attorney Joseph McCann, Attorney Advisor