REGENERON

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December 7, 2020

VIA EDGAR

U.S. Securities and Exchange Commission
Division of Corporation Finance
Office of Life Sciences
100 F Street, NE
Washington, D.C. 20549

Re: Regeneron Pharmaceuticals, Inc.
Form 10-K for the fiscal year ended December 31, 2019
Filed on February 7, 2020
Form 10-Q for the quarterly period ended September 30, 2020
Filed on November 5, 2020
File No. 0-19034

Dear 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 Securities and Exchange Commission (the "Commission") set forth in the Staff's letter dated November 20, 2020, with respect to the above-referenced Form 10-K and Form 10-Q.

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

Form 10-K, Filed February 7, 2020

Item 10. Directors, Executive Officers and Corporate Governance, page 76

1. We note the following statement on page 26 of the proxy statement that has been incorporated by reference "[t]he board has determined that this leadership structure is appropriate for the Company at this time." In future filings, please provide detail concerning why you have determined that this leadership structure is appropriate given your specific characteristics or circumstances as required by Item 407(h) of Regulation S-K.

Response:

We believe that the disclosure set forth in the first paragraph under the heading "Board Leadership and Role in Risk Oversight" on page 26 of the proxy statement describing the qualifications of the Chairman of Regeneron's Board of Directors and his role vis-à-vis the Board of Directors and the Chief Executive

Officer is responsive to Item 407(h) of Regulation S-K. However, in future filings, we will revise our disclosure to clarify further why we have determined that our leadership structure is appropriate given our specific characteristics or circumstances.

Item 11. Executive Compensation, page 76

2. We note your reference to a share repurchase program in the Compensation Discussion and Analysis section of the definitive proxy statement that is incorporated by reference, and the disclosure in your Form 10-K of the repurchases that occurred in 2019. Please tell us why you do not discuss in your CD&A the impact of share repurchases on your compensation levels in 2019.

Response:

We did not discuss in our most recent CD&A the impact of our share repurchases on our executive compensation levels in 2019 because we do not believe our repurchases had a material impact on our executive compensation levels in 2019. Therefore, we do not believe that a discussion of those repurchases would have provided material information necessary to an understanding of the compensation program applicable to our named executive officers in 2019. In particular, we note that the 2019 executive compensation program did not utilize earnings-per-share metrics or other similar metrics directly impacted by the number of outstanding shares of Regeneron common stock reduced as a result of stock repurchases that occurred in 2019.

Form 10-Q for the Quarterly Period Ended September 30, 2020

Notes to Condensed Consolidated Financial Statements (Unaudited)
1. Interim Financial Statements
Basis of Presentation, page 7

3. We note your disclosure that effective January 1, 2020 you changed the presentation of cost reimbursements from collaborators who are not deemed to be your customers from collaboration revenue to a reduction of the corresponding operating expense. We note that you also changed the presentation of amounts recognized in connection with up-front and development milestone payments from collaboration revenue to other operating income. Please provide us with your full analysis supporting this change and its impact on each element of your collaboration agreements. In particular, please explain why you changed your conclusion regarding whether your collaborators were deemed to be customers and how this impacted your application of applicable revenue recognition guidance.

Response:

Background
The Company is a party to collaboration agreements to develop and commercialize, as applicable, certain products and product candidates. Effective January 1, 2020, the Company implemented changes in the presentation of its financial statements related to certain reimbursements and other payments for products developed and commercialized with collaborators. We note by way of background:

- The Company has entered into various collaborative arrangements. At the inception of each of these arrangements, the Company and its collaborator were each deemed to be active participants in the collaborations' joint operating activities and were exposed to significant risks and rewards

dependent on the commercial success of the activity (*e.g.*, profit sharing, sales milestones, etc.). Accordingly, the arrangements were deemed to be collaborations in accordance with ASC 808, *Collaborative Arrangements*.

- Historically, the Company made a determination that its collaborative arrangements, including those with Sanofi, Bayer, Teva, and Mitsubishi Tanabe Pharma Corporation ("MTPC"), fell within the scope of ASC 808. Given the lack of prescriptive guidance in ASC 808 and the fact that performance of research and development ("R&D") activities was part of Regeneron's ongoing major or central operations, the Company previously presented reimbursements and other payments from its collaborators by analogy to revenue guidance (initially ASC 605, *Revenue Recognition*, and subsequently ASC 606, *Revenue from Contracts with Customers*) pursuant to ASC 808-10-45-3 and 45-4 (as originally codified).
- The Company's ongoing major or central operations have evolved from being responsible for providing R&D activities in exchange for consideration to being a "fully integrated biotechnology company" with significant commercial operations (as described in the Company's Form 10-K for the year ended December 31, 2019). The evolution is evidenced by the fact that Regeneron has entered into arrangements whereby its collaborators are responsible for conducting R&D activities in exchange for funding provided by Regeneron. In addition, the Company has been conducting commercialization activities for products that have received regulatory approval. By way of example, through 2016, the Company was performing commercialization activities solely for ARCALYST® (rilonacept) and EYLEA® (aflibercept); from 2017 to 2019, four additional products received marketing approval for which the Company conducts various commercialization activities. We believe that the Company's historical primary activities were consistent with the roles and responsibilities assumed by "Biotech", and that our current primary activities are consistent with the roles and responsibilities assumed by "Pharma", in the illustrative examples included in ASC 808-10-55. Consequently, we believe that it was appropriate to change our accounting presentation for certain reimbursements and other payments from our collaborators to be presented in accordance with ASC 808.
- In addition to the evolution of the Company's ongoing or central operations, there have been changes to the Company's roles and responsibilities within our existing collaborative arrangements. Most notably, in December 2019, we and Sanofi announced our intent to restructure the collaboration for Praluent® and enter into a royalty-based arrangement. The restructuring, which was effective April 1, 2020, resulted in fundamental changes to parties' respective rights and obligations under the collaboration.

Based on the above considerations as well as the analysis below, we believe it is appropriate and preferable to present certain reimbursements and other payments from collaborators outside of revenue. The Company made these changes in presentation effective January 1, 2020 to better reflect the nature of the Company’s costs incurred and revenues earned pursuant to arrangements with collaborators and to enhance the comparability of Regeneron's financial statements with industry peers.

Historical Facts and Circumstances

Historically, a significant portion of the Company's business was related to performing R&D activities in connection with collaborative arrangements, as evidenced by the arrangements summarized below (detailed information related to each of the Company's significant collaborative arrangements can be found in the Company's Form 10-K for the year ended December 31, 2019):

- **Bayer – EYLEA**. Since 2006, we and Bayer have been parties to a global license and collaboration agreement for the development and commercialization outside the United States of EYLEA. EYLEA was in Phase 2 clinical studies at the time of entering into the arrangement, and it ultimately received U.S. Food and Drug Administration ("FDA") and other marketing approvals outside the United States commencing in 2011. At the inception of the collaboration agreement,

Regeneron was responsible for leading the worldwide development activities. Bayer is responsible for commercialization activities for EYLEA outside the United States and the Company is responsible for commercialization of EYLEA in the United States.

- **Sanofi – Antibodies**. Since 2007, we and Sanofi have been parties to a global, strategic collaboration to research, develop, and commercialize fully human monoclonal antibodies. The collaboration was governed by a Discovery and Preclinical Development Agreement ("Antibody Discovery Agreement") and a License and Collaboration Agreement (each as amended), collectively referred to as the "Antibody Collaboration". Pursuant to the Antibody Discovery Agreement, as amended, Sanofi was responsible for funding up to a specified amount of our antibody discovery activities each year to identify and validate potential drug discovery targets and develop fully human monoclonal antibodies against these targets. We led the design and conduct of research activities under the Antibody Discovery Agreement, including target identification and validation, research and preclinical activities, and manufacturing of preclinical and clinical supplies. The Company's Antibody Discovery Agreement with Sanofi ended on December 31, 2017 (see "Current Facts and Circumstances" section below).

  For each drug candidate identified through discovery research under the Antibody Discovery Agreement, Sanofi had the option to license rights to the candidate under the License and Collaboration Agreement. If it elected to do so, Sanofi would co-develop the drug candidate with us through product approval. Sanofi leads commercialization activities for products developed under the License and Collaboration Agreement, subject to the Company's right to co-commercialize such products.

- **Sanofi – Immuno-Oncology**. In 2015, we 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 IO Collaboration is governed by an Immuno-oncology Discovery and Development Agreement ("IO Discovery Agreement"), and an Immuno-oncology License and Collaboration Agreement ("IO License and Collaboration Agreement") (each as amended). In connection with the IO Discovery Agreement, Sanofi made an up-front payment to us. Pursuant to the original IO Discovery Agreement, we agreed to spend up to a certain amount to identify and validate potential targets and develop antibodies against such targets through clinical proof-of-concept. Sanofi agreed to reimburse us for up to a certain portion of these costs. Pursuant to the IO Discovery Agreement, we were primarily responsible for the design and conduct of all research activities, including target identification and validation, preclinical activities, manufacture of preclinical and clinical supplies, and clinical development. With regard to product candidates for which proof-of-concept is established, Sanofi had the option to license rights to the product candidate pursuant to the IO License and Collaboration Agreement.

  Under the terms of the IO License and Collaboration Agreement, Sanofi made an up-front payment to the Company, and the parties were (and are currently) co-developing and co-commercializing Libtayo® (cemiplimab). The parties share equally, on an ongoing basis, agreed-upon development and commercialization expenses for Libtayo. The Company has principal control over the development of Libtayo and leads commercialization activities in the United States, while Sanofi leads commercialization activities outside of the United States.

- **Fasinumab.** In 2015, we entered into a collaboration agreement with MTPC providing them with development and commercial rights to fasinumab in certain Asian countries. In connection with the agreement, MTPC made an up-front payment to the Company, and the Company is obligated to manufacture and supply MTPC with clinical and commercial supplies of fasinumab.

In 2016, the Company and Teva entered into a collaboration agreement to develop and commercialize fasinumab globally, excluding certain Asian countries that are subject to the Company's collaboration agreement with MTPC. In connection with the Teva Collaboration Agreement, Teva made an up-front payment to the Company. We lead global development activities, and the parties share equally, on an ongoing basis, development costs under a global development plan.

At the inception of each of these arrangements, the Company and its collaborator were each deemed to be active participants in the collaborations' joint operating activities and were exposed to significant risks and rewards dependent on the commercial success of the activity (*e.g.*, profit sharing, sales milestones, etc.). Accordingly, the arrangements were deemed to be collaborations in accordance with ASC 808. In addition, the collaborators were deemed to be the Company's "customer" (by analogy to ASC 605 and subsequently ASC 606) for certain elements of the arrangement, as the collaborator was providing consideration in exchange for the Company providing goods/services (*e.g.*, license to intellectual property ("IP") and R&D services, including manufacturing) utilizing its proprietary technology. Such elements were accounted by applying ASC 606 by analogy because the performance of R&D services was considered to be part of Regeneron’s ongoing major or central operations at the inception of these arrangements. The treatment of bifurcating elements within a collaboration arrangement accounted for under ASC 808 is implicitly permitted in ASC 808 (pre-issuance of ASU 2018-18, *Collaborative Arrangements*) and occurs in practice. This treatment was later explicitly permitted through the issuance of ASU 2018-18 which the Company adopted on January 1, 2020. In addition, the treatment of consideration received in exchange for the performance of R&D services as revenue is illustrated in Example 1 and 2 of ASC 808-10-55-3 through 55-10.

In determining the historical presentation of reimbursements from its collaborators, we considered the below guidance from ASC 808-10 (as originally codified):

> ***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.*
>
> ***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.*

Considering the above authoritative guidance, in connection with an assessment of the nature of the arrangements and an assessment of our business operations (including the Company's cash generating activities) at the inception of these arrangements, the Company deemed these collaborators to be its customers by analogy. Accordingly, the Company presented reimbursements from such collaborators "gross" (*i.e.*, within revenue) rather than "net" (*i.e.*, as an offset to the corresponding expense incurred). Specifically, we consistently applied the below accounting for amounts received and/or amounts reimbursed from the Company's collaborators:

- **Up-front and development milestone payments** – in arrangements where the Company received an up-front payment from its collaborators and determined that its obligations formed a combined unit of account (*i.e.*, license and R&D services), the Company recognized such amounts, as well as any subsequent development milestones earned, as revenue.
- **Reimbursement of R&D activities (including manufacture of clinical supplies)** – the Company recorded its internal and third-party development costs as R&D expense, and where the Company was entitled to reimbursement of a portion or all of the R&D expenses that it incurred, the Company recorded those reimbursable amounts as revenue.
- **Reimbursement of commercialization-related activities** – the Company recorded its internal and third-party commercialization-related costs as Selling, General & Administrative ("SG&A") expense, and where the Company was entitled to reimbursement of a portion or all of the SG&A expenses that it incurred, the Company recorded those reimbursable amounts as revenue.
- **Reimbursement of commercial supplies** – the Company recorded its manufacturing costs associated with products subject to the respective agreements as Cost of collaboration and contract manufacturing ("COCM"), and where the Company is entitled to reimbursement of a portion or all of the COCM expenses that it incurs, the Company recorded those reimbursable amounts as revenue.
- **Royalties, share of profits, and sales-based milestone payments** – the Company recorded royalties, its share of profits in connection with commercialization of products by its collaborator, and sales-based milestone payments as revenue.

Current Facts and Circumstances

We note that the Company's overall business has developed and changed over time, and the nature and extent of some of the above noted collaborative arrangements have also changed since the original execution of such agreements. The change in the Company's primary business is evidenced by the following events/transactions that occurred recently:

- **The Company's broad, discovery-based arrangements (where the Company was engaged, and paid, by a collaborator to utilize our expertise to discover and research targets/product candidates) have ended or have had the scope narrowed**
    - The Company's Antibody Discovery Agreement with Sanofi ended on December 31, 2017 without any extension and, therefore, funding from Sanofi under the Antibody Discovery Agreement for broad-based target discovery ceased after 2017.
    - The Company and Sanofi entered into an amended IO Discovery Agreement, effective December 31, 2018, which narrowed the scope of the existing discovery and development activities conducted by the Company under the 2015 IO Discovery Agreement to developing two therapeutic bi-specific antibodies through clinical proof-of-concept.
- **The Company has received regulatory approval and has commercialized, either independently or with its collaborator, several new products since 2010 (note: list below is not meant to be all-inclusive)**
    - As of December 31, 2010, the Company had one marketed product, ARCALYST, which had $25 million of net product sales during 2010 and was only approved in the United States. This represented approximately 6% of the Company's total revenues in 2010.
    - We commenced commercialization of EYLEA in the United States in 2011, and Bayer commenced commercialization of EYLEA outside the United States in 2012.
    - Sanofi commenced commercialization of Praluent, Dupixent, and Kevzara globally in 2015, 2017, and 2017, respectively.
    - More recently, in October 2018, the Company commenced selling Libtayo in the United States (and Sanofi has since commenced commercialization of Libtayo outside the United States).

- In connection with the restructuring of the Sanofi Antibody collaboration (as described below), the Company took over responsibility from Sanofi to commercialize Praluent in the United States effective during 2020.
- As of December 31, 2019, the Company had seven products that have received marketing approval, which had global net product sales in 2019 of more than $10 billion.

- **Certain collaborators have taken the lead on executing development activities for products subject to our collaborations**
  - For example, at the inception of the Sanofi collaboration agreements, Regeneron was generally responsible for executing most development activities (*i.e.*, an example of a historical contractual arrangement under which we were providing R&D services to our collaborator). By contrast, for products on which we are currently collaborating with Sanofi, Sanofi has taken the lead on various development activities, including leading several clinical trials (*e.g.*, Dupixent in asthma and REGN3500 in chronic obstructive pulmonary disease ("COPD")).
- **The Company has been increasing the number of early-stage, broad-based research and discovery arrangements to provide initial (*i.e.*, up-front) and on-going funding to collaborators for the discovery, research, and/or development of clinical targets (note: list below is not meant to be all-inclusive and detailed information related to each of the below arrangements can be found in the Company's respective Form 10-K for the year in which the arrangement was entered into)**
  - In 2016, we entered into a license and collaboration agreement with Intellia Therapeutics, Inc. Intellia is the lead party for the first target selected by the Company. In connection with the execution of the agreement, we made a $75 million up-front payment and are responsible for funding certain research and development costs.
  - In 2018, we entered into a collaboration agreement with bluebird bio, Inc. Under the terms of the agreement, the parties equally share the costs of research and development, which is currently led by bluebird. In connection with the execution of the agreement, we made a payment of $37 million for the prepayment of R&D activities.
  - In April 2019, we entered into a global, strategic collaboration with Alnylam Pharmaceuticals, Inc. We made an up-front payment of $400 million to Alnylam; and for each program, we will provide Alnylam with a specified amount of funding at program initiation and at lead candidate designation, and Alnylam is eligible to receive up to $200 million in clinical proof-of-principle milestones.
  - In November 2019, we entered into a research collaboration and option licensing agreement with Vyriad, Inc. Vyriad is primarily responsible for research and development activities. In connection with the execution of the agreement, we made an aggregate of $30 million in up-front payments to Vyriad and are obligated to provide research funding over the research term.

In addition, a significant portion of the Company's revenues earned in 2019 were related to commercialization of products (whether sold by us or our collaborator). For example, net product sales for products commercialized by Regeneron represented over 60% of the Company's 2019 total revenues, and another 16% was generated from our share of profits in connection with commercialization of products by Sanofi and Bayer.

We believe that the points noted above evidence that:

- The Company's primary business is no longer providing R&D services. In this regard, we have not recently entered into any broad-based discovery arrangements where Regeneron is the party primarily responsible for R&D services, and our collaborators are taking the lead on many research and development activities (with funding by Regeneron).

- The Company has successfully developed a commercial function and has demonstrated the ability to independently commercialize products across multiple indications.
- The Company has been generating a significant portion of its revenues from commercialization of products, whether through independently selling such or sharing profits/getting paid royalties on product sales by a collaborator.

In addition, we and Sanofi announced in December 2019 our intent to restructure the Antibody Collaboration for Praluent and enter into a royalty-based arrangement. Effective April 1, 2020, Sanofi gained sole global rights to Praluent outside of the United States and Regeneron gained sole U.S. rights to Praluent. In accordance with the revised agreement, each party is solely responsible for funding development and commercialization expenses in its respective territory. The restructuring resulted in fundamental changes to the parties' respective rights and obligations under the Antibody Collaboration, and as a direct result, changed the corresponding economics of the arrangement. This further demonstrates the recent shift in the Company's business operations.

Based on the above factors, we believe that the Company's primary business is currently developing IP and monetizing such through its own commercialization, commercialization by collaborators, and the licensure to third parties for future consideration.

In noting the above change to the Company's primary business, and considering the amendments to the Antibody Collaboration, we believe that it was appropriate to reassess whether Sanofi should continue to be deemed the Company's "customer" (by analogy) for accounting purposes. As described above, the parties' roles and responsibilities have changed, with Sanofi no longer solely obtaining the output of the Company's primary activities (*i.e.*, R&D activities, as was the case at the inception of the contract) and both parties now taking the lead on various activities for the collaboration (*e.g.*, Sanofi taking the lead on various development activities and participating in manufacturing activities, and the Company participating in commercialization-related activities, etc.). In accordance with ASC 606, revenue is defined as "inflows or other enhancements of assets of an entity or settlements of its liabilities (or a combination of both) from delivering or producing goods, rendering services, or other activities that constitute the entity's **ongoing major or central operations** [emphasis added]." Accordingly, a reassessment of the accounting for the arrangement based on the current facts and circumstances caused management to conclude that Sanofi should be treated not as its "customer" by analogy but rather as its "collaborator," and thus, inflows received from Sanofi pursuant to the Antibody Collaboration would no longer be presented within revenue as such inflows would not be paid in exchange for the output of the Company's current ongoing major or central operations.

In consideration of the change in facts and circumstances since the inception of these collaboration agreements (as described above), we also believe that it was appropriate to reassess and change the presentation of certain reimbursements and other payments received from the Company's other collaboration agreements (*i.e.*, Sanofi IO, Bayer, Teva, and Mitsubishi).

Change in Presentation for Reimbursements and Certain Other Payments from Collaborators

We considered the guidance within ASC 250-10, *Accounting Changes and Error Corrections* (paragraphs 45-1, 45-2, and 45-12), related to changes in accounting principle. A voluntary change in accounting principle can be a change from one generally accepted accounting principle to another generally accepted accounting principle when there are two or more generally accepted accounting principles that apply (*e.g.*, the presentation of reimbursements from its collaborators "gross" or "net"). Further, ASC 250-10-55-1 states "...preferability among accounting principles shall be determined on the basis of whether the new principle constitutes an improvement in financial reporting and not on the basis of the income tax effect alone."

SAB Topic 6.G(2)(b)1, *Reporting Requirements for Accounting Changes* (codified in ASC 250-10-S99-4) provides additional information to help assess management's obligation in evaluating whether a proposed accounting change is preferable. The SAB indicates that management’s plans and judgments that are made in good faith are major considerations in determining whether a change is to a preferable accounting principle.

We believe that the change in presentation of reimbursements from collaborators from "gross" to "net," and the presentation of amounts recognized in connection with up-front and development milestone payments from collaborators within other operating income, is preferable based on the following:

- **Qualitative Factors:**
  - **Authoritative support:**
    - The Financial Accounting Standards Board ("FASB") issued ASU 2018-18, which was effective for fiscal years beginning after December 15, 2019. The guidance in ASC 808 is non-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 based on an analogy to other US GAAP guidance, or a reasonable, rational and consistently applied policy election, if there is no appropriate analogy.
    - In considering the clarifications to ASC 808 as a result of the issuance of ASU 2018-18, we considered the below amended ASC 808 guidance (which effectively combined paragraph 45-3 and 45-4 (cited above) into a single paragraph of the guidance):

      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.*

    - We additionally considered the below paragraphs from the Background Information and Basis for Conclusions of ASC 808, which notes, among other things, the FASB's acknowledgement that there exists diversity in practice and there is no "one-size-fits-all" accounting model for "nonrevenue" collaborative arrangements:

      BC32.*The FASB staff explored a potential nonrevenue model that was flexible and would have allowed an entity to reflect the underlying economics of*

the collaborative arrangement. That model intentionally left substantial room for judgment to allow for different accounting outcomes for a wide range of arrangements that had significant differences in economics. Under that model, once a collaborative arrangement participant determined that an identified unit of account was outside the scope of Topic 606, it would recognize a transaction as either a reduction of cost or other income depending on whether the nature of the underlying transaction was related to a specific and identifiable cost incurred in accordance with the collaboration agreement (using concepts from Topic 606).

BC33. *In December 2017, the FASB hosted two workshops for preparers and auditors to provide feedback on the operability of the staff's potential nonrevenue model. Because of the proposed model's flexibility, certain participants raised concerns that the model would be difficult to apply and that it may not solve many of the challenges raised about recognition. Specifically, certain participants indicated that the potential model would not remove the difficulties in determining an activity's underlying nature, allocating consideration to interrelated activities, and determining the recognition period for a unit of account. Overall, the feedback received during the workshops made it clear that if a nonrevenue model was developed, practice would desire more prescriptive guidance; however, there were strong opposing views on what that guidance should be. Because of the diverse views and various issues raised, the Board concluded that it would have been difficult to develop a "one-size-fits-all" accounting model for the various types of collaborative arrangements, particularly within the context of this project on targeted improvements for collaborative arrangements. Therefore, the Board decided not to provide recognition and measurement guidance for nonrevenue transactions in a collaborative arrangement.*

- We note that in collaborative arrangements where its obligations form a combined unit of account (*i.e.*, license and R&D services), the Company views contractually mandated cost reimbursements differently from both up-front (*i.e.*, "buy-in") payments and contingent milestone payments. Accordingly, with regards to the amounts recognized in connection with up-front and development milestones being presented separately (*i.e.*, in other operating income) from reimbursements from collaborators (*i.e.*, as a reduction of the corresponding expense incurred), we determined it was acceptable to employ a reasonable, rational, and consistently applied accounting policy to present up-front and milestone payments on a different income statement line item from the reimbursement for R&D services.

  In making this determination, we considered the guidance pursuant to the Securities and Exchange Commission's Regulation S-X Rule 5-03, *Statements of comprehensive income*, which remains intact after the issuance of ASC 606 and requires a registrant to state material revenue streams separately (*i.e.*, in more than one line item) on the face of their income statement based on their nature.

  In addition to considering the above referenced guidance, we note that a number of our peers in the biotechnology/pharmaceutical industry appear to present upfront/development milestone payments in a different line item from cost reimbursements.

Therefore, the Company ultimately determined that separating these forms of consideration into different line items on the income statement is acceptable and consistent with industry practice.

- **Rationality:**
  - The change:
    - Represents a more accurate reflection of the Company's costs and revenues given the nature of the Company's current business operations and current arrangements with collaborators.
    - Aligns more closely with the substance of the collaboration events/transactions being recognized (*i.e.*, reimbursement of corresponding expenses incurred by the Company).
  - The change in presentation is appropriate in light of changes in the Company's primary business (as described above). We note, pursuant to ASC 250 and SAB Topic 6, that business judgment and business planning often are major considerations in determining that the change is to a preferable method because the change results in improved financial reporting.
  - We historically provided forward-looking financial guidance, as well as actual financial results, to investors, analysts, and internal stakeholders (*i.e.*, members of senior management and the Board of Directors) related to "Unreimbursed R&D" expense (which is calculated as R&D expenses reduced by R&D expense reimbursements), as we viewed this as an important metric of the Company's financial performance. Thus, the change in the presentation of the Company's financial statements served to more closely align to this metric utilized by investors, analysts, and internal stakeholders. Accordingly, we no longer require separate presentation of "Unreimbursed R&D" as a metric as it will be captured in our financial statement line item.

- **Industry practice:**
  - We acknowledge that diversity in practice exists with respect to the presentation of cash inflows from collaborative arrangements. However, based on our review of publicly available financial statements, "net" presentation is a widely recognized practice in the biotechnology/pharmaceutical industry.
  - In addition to "net" presentation of reimbursements, we also note that several of these same companies appear to present amounts recognized in connection with up-front and development milestone payments earned under such arrangements as other operating income or revenue (as applicable). These examples demonstrate an industry practice of presenting inflows from up-front and development milestone payments in a separate financial statement caption from reimbursements received from a collaborator.

- **Quantitative Factors:**
  - As described in Note 1 of the Company's Forms 10-Q for each of the quarterly periods during 2020, the financial statement accounts impacted by the change in accounting policy were as follows:
    - Balance sheet – Certain balance sheet captions were renamed (*e.g.*, Deferred revenue) to disaggregate existing balances between customer and non-customer arrangements.
    - Statement of Operations – The change in presentation resulted in lower revenue and lower expense (R&D, SG&A, and COCM) by corresponding amounts. However, there was no impact to income from operations, net income, or earnings per share.

- **We additionally considered the financial statement disclosure implications related to the voluntary change in accounting principle, noting the following:**
  - The Company has disclosed the nature of and justification for the change as well as the effects of the change on net income (*i.e.*, no impact) for the period in which the change is made. Furthermore, the disclosure of the change explains why the newly adopted principle is preferable to the previously-applied principle. See Note 1 of the Company's Forms 10-Q for each of the quarterly periods during 2020.
  - As required by S-X 10-01(b)(6), a letter from our auditors, PricewaterhouseCoopers LLP, indicating that the change, in their judgment, is preferable under the circumstances is included as Exhibit 18 attached to the Company's Form 10-Q for the quarterly period ended March 31, 2020.
  - As it relates to significant collaborative arrangements (*i.e.*, Sanofi, Bayer, and other significant collaborative arrangements that may arise in the future), the Company will continue to disclose the amounts of reimbursements received from collaborators in a disaggregated manner, where on the Statement of Operations such reimbursements have been presented, and the Company's accounting policy for collaborative arrangements. See Note 3 of the Company's Forms 10-Q for each of the quarterly periods during 2020.

Conclusion

Based on the above considerations, we believe it is appropriate and preferable to present certain reimbursements and other payments from collaborators outside of revenue. The Company made these changes in presentation to better reflect the nature of the Company's costs incurred and revenues earned pursuant to arrangements with collaborators and to enhance the comparability of Regeneron's financial statements with industry peers. Consequently, we have applied the below accounting policies for amounts received and/or amounts reimbursed in such arrangements, and we have reclassified prior-period amounts presented in our financial statements to conform with the new presentation.

- **Up-front and development milestone payments –** in arrangements where the Company receives an up-front payment and development milestone payments from its collaborator and determines that its obligations form a combined unit of account (*i.e.*, license and R&D services), the Company recognizes such amounts as Other operating income.
- **Reimbursement of R&D activities (including manufacture of clinical supplies)** – the Company records its internal and third-party development costs as R&D expense, and where the Company is entitled to reimbursement of a portion or all of the R&D expenses that it incurs, the Company records those reimbursable amounts as a reduction to R&D expense.
- **Reimbursement of commercialization-related activities** – the Company records its internal and third-party commercialization-related costs as SG&A expense, and where the Company is entitled to reimbursement of a portion or all of the SG&A expenses that it incurs, the Company records those reimbursable amounts as a reduction to SG&A expense.

In addition, it should be noted that we have not changed our historical accounting presentation for amounts received and/or amounts reimbursed in connection with the following transactions from our collaborative arrangements:

- Reimbursement of commercial supplies
- Royalties, share of profits, and sales-based milestone payments

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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
Executive Vice President, Finance and
Chief Financial Officer