

VERTEX PHARMACEUTICALS INCORPORATED 50 NORTHERN AVENUE • BOSTON, MA 02210-1862 TEL. 617-341-6100 • http://www.vrtx.com

FOIA Confidential Treatment Request The entity requesting confidential treatment is Vertex Pharmaceuticals Incorporated 50 Northern Avenue Boston, MA 02210 Attn: Michael J. LaCascia, Senior Vice President and General Counsel

October 19, 2016

Delivered via EDGAR

Securities and Exchange Commission Division of Corporation Finance 100 F Street, N.E. Mail Stop 4546 Washington, DC 20549

Attn: Sharon M. Blume, Accounting Branch Chief Office of Healthcare and Insurance

Re: Vertex Pharmaceuticals Incorporated Form 10-K for the Fiscal Year Ended December 31, 2015 Filed February 16, 2016 File No. 000-19319

Ladies and Gentlemen:

The purpose of this letter is to respond to the comments from the staff (the "<u>Staff</u>") of the Securities and Exchange Commission (the "<u>Commission</u>") to Vertex Pharmaceuticals Incorporated (the "<u>Company</u>") set forth in the Staff's letter to Jeffrey M. Leiden, dated September 30, 2016 (the "<u>Comment Letter</u>"), regarding the Company's Form 10-K for the fiscal year ended December 31, 2015. The comments from the Comment Letter are reproduced below together with the Company's responses to the comments. The Company is seeking confidential treatment for portions of this letter pursuant to Rule 83 of the Freedom of Information Act (FOIA).

Notes to Consolidated Financial Statements B. Collaborative Arrangements Variable Interest Entities (VIE) Parion Sciences, Inc., page F-19

Comment 1

ASC 810-10-25-22 states that the variability to be considered in the consolidation analysis is based on an analysis of the design of the entity and provides a two-step test. Please describe for us your analysis of:

· Parion's design, including the nature of the risks in the entity, and

• The purpose for which Parion is created and the variability that Parion is designed to create and pass along to interest holders.

Response 1

Confidential Treatment Requested by Vertex Pharmaceuticals Incorporated pursuant to Rule 83, Request #1

As disclosed on its website, Parion Sciences, Inc. ("Parion") was "originally founded on advancing [its] proprietary epithelial sodium channel ("ENaC") blockers for pulmonary disease." To further this purpose, Parion has focused its efforts on the research and development of investigational ENaC inhibitors, including VX-371 (formerly P-1037) and VX-551 (formerly P-1055), for the potential treatment of cystic fibrosis and all other pulmonary diseases. Since its founding Parion has expanded its research and development into other disease areas, [**], including P-321, which is being developed by Parion for the treatment of dry eye disease, and Parion's trans-nasal pulmonary aerosol delivery ("tPAD") system, which is being developed by Parion for use in the treatment of cystic fibrosis and chronic obstructive pulmonary disease. Each of these other research and development programs are either pre-clinical or in early stages of development. Based on the foregoing, the purpose and design of Parion is [**] (the "Licensed Assets") [**].

In connection with the above activities, Parion is exposed to the following significant risks: (i) research and development risks – including that pre-clinical and clinical data from its research and development programs may not support further development of its drug candidates due to safety, efficacy or other reasons, (ii) regulatory risks – including that Parion may be unable to obtain marketing approval for one or more of its drug candidates, (iii) commercialization risks, including that Parion may be unable to successfully commercialize a drug candidate that obtains marketing approval, whether it be due to safety or efficacy issues that arise, the introduction or greater acceptance of competing products, changes in reimbursement policies of payors or for any other reason and (iv) financial risks, including the potential of not having sufficient resources to bring a drug candidate through the development and commercialization process. Prior to the date of the strategic collaboration and license agreement (the "<u>Agreement</u>") with the Company, Parion's stockholders were the sole variable interest holders in Parion and would absorb all potential expected losses if its research and development programs were unable to support commercialization of its drug candidates and would receive all potential residual returns from drug candidates that were successfully commercialized after obtaining marketing approval.

On May 31, 2015, Parion had [**]. Parion could have elected to seek to fund future research and development activities through the issuance of additional equity and/or debt, in which case Parion's stockholders would have continued to absorb the variability associated with its research and development programs. Instead Parion chose to collaborate with the Company by granting the Company a license (the "License") to the Licensed Assets and ceded control over all significant decisions with respect to the research, development and potential commercialization of the Licensed Assets to the Company.

Pursuant to the Agreement, the parties agreed that the Company would (i) assume control over the development of the Licensed Assets, (ii) assume responsibility for all costs, subject to certain exceptions, related to the development of the Licensed Assets and (iii) have the right to commercialize drug candidates that obtain marketing approval and to receive financial rewards from such commercialization, subject to the payment of royalties and milestones to Parion. The result of this contractual arrangement is that the Company will (a) absorb expected losses if further development does not support commercialization of the Licensed Assets and (b) receive a significant majority of the residual returns from the Licensed Assets if further development supports commercialization. The

fair value of the License therefore fluctuates in parallel with the development progress of the Licensed Assets. The Company, through the license, absorbs the expected losses in the fair value of the Licensed Assets (and the related decrease in the value of the License) because if the development activities under the Agreement do not support commercialization of the Licensed Assets and a program is terminated, the Company will have paid the upfront payment and potential milestone payments, as well as the cost of all of the development activities of the terminated program. On the other hand, the Company will receive a significant majority of the potential residual returns from the Licensed Assets (and the related increase in the value of the License) if they are successfully developed since the Company has the right to commercialize any such approved drug candidate, subject only to the payment of royalties and milestones to Parion.

As a result of the Agreement, Parion was redesigned with the Company assuming a significant majority of the variability that the entity was designed to create and pass along to interest holders.

The Company respectfully requests that the information contained in the above response that have been marked [**] be treated as confidential information and that the Commission provide timely notice to Michael J. LaCascia, the Company's Senior Vice President and General Counsel, 50 Northern Avenue, Boston, Ma 02210, (617) 961-7018, before it permits any disclosure of the information in the above response.

Comment 2

Please describe for us how the contractual arrangement between Vertex and Parion absorbs the variability that Parion was designed to create and pass along to interest holders.

Response 2

Confidential Treatment Requested by Vertex Pharmaceuticals Incorporated pursuant to Rule 83, Request #2

As stated above in the Company's response to Comment #1, Parion's purpose and design is to [**]. Prior to entering into the Agreement, Parion had [**]. Parion created the License in order to [**]. Please refer to the Company's response to Comment #1 above, for how the License absorbs a significant majority of the variability that Parion is designed to create and pass along to its interest holders (i.e., the Company and Parion's stockholders).

As set forth in the Company's Response Letter dated August 12, 2016, the License is a contractual arrangement in specified assets [**]. Therefore, the Company determined that the License represented a variable interest in Parion as a whole. This assessment was performed in accordance with ASC 810-10-25-55.

Comment 3

As noted in your response to comment 4 within your August 12 letter, you have determined that Parion's other research and development programs (i.e. the Non-Licensed Asset Programs) had minimal value and therefore any limitations over your power with respect to these activities is not significant. ASC 810-10-25-38B requires a reporting entity to identify which activities most significantly impact the VIE's economic performance and determine whether it has the power to direct those activities. Notwithstanding the value of Parion's assets as of the reporting date, please describe how you determined that (i) substantially all the activities of Parion are on the behalf

of Vertex and (ii) the research, development, and commercialization of the licensed assets represent the activities of Parion expected to most significantly impact its economic performance. Please address the following in your response:

- The overall operational and financial decisions of Parion, as well as decisions over the \$80M initial payment under the Agreement (and any contingent milestone payments) retained within Parion are directed by Parion Management or its Board of Directors.
- The Collaboration Agreement expires at the later of 1) the patent period of the Licensed Assets, or 2) 10 years after the first commercial sale per country, while Parion the entity appears to have an indefinite life.
- As stated on its website, Parion is a development stage company dedicated to research, development, and commercialization of treatments to restore innate mucosal surface defenses. Further describing the entity's technologies as targeting both respiratory and ocular diseases.
- Parion's website refers to press releases dated January 19, 2016 and May 2, 2016 which refer to further development and collaboration efforts over Parion Selected Assets.

The Company respectfully requests that the information contained in the above response that that have been marked [**] be treated as confidential information and that the Commission provide timely notice to Michael J. LaCascia, the Company's Senior Vice President and General Counsel, 50 Northern Avenue, Boston, Ma 02210, (617) 961-7018, before it permits any disclosure of the information in the above response.

Response 3

Confidential Treatment Requested by Vertex Pharmaceuticals Incorporated pursuant to Rule 83, Request #3

Prior to entering into the Agreement, Parion [**]. Additionally, although the Company does not participate in the operational or financial decisions of Parion as an entity, the Company controls all significant decisions with respect to the research, development and potential commercialization of the Licensed Assets. [**] are associated with development of the Licensed Assets and [**] from the Licensed Assets. As a result, Parion's economic performance is tied to the development of the Licensed Assets over which the Company has ultimate decision making authority. The Company determined that the research, development, and commercialization of the Licensed Assets represented (and continues to represent) [**]. Since the activities that significantly impact Parion's economic performance are directed by multiple unrelated parties as discussed further below, the Company considered what activities are expected to most significantly impact its economic performance. This assessment is consistent with the identification of a primary beneficiary as discussed in ASC 810-10-25-38E, which states:

"If the activities that impact the VIE's economic performance are directed by multiple unrelated parties, and the nature of the activities that each party is directing is not the same, then a reporting entity shall identify which party has the power to direct the activities that most significantly impact the VIE's economic performance. One party will have this power, and that party shall be deemed to have the characteristic in paragraph 810-10-25-38A(a)."

The significant activities of Parion include the following:

• Research and development of the Licensed Assets;

- Commercialization of the Licensed Assets;
- · Research, development and potential commercialization of non-licensed assets; and
- · Operational and financial decisions of Parion as an entity.

The Company believes the activities related to the research and development of the Licensed Assets, as outlined below, [**], each of which are overseen by the Joint Steering Committee, [**] (as described in the Company's responses to Comments #3 and #4 in the Company's response letter dated August 12, 2016):

- Preparation of a development plan for each Licensed Asset and preparing clinical trial designs and protocols;
- Conducting clinical trials under the development plan and providing strategic oversight with respect to development of the Licensed Assets;
- Reviewing and analyzing all data (including clinical trial data) and updates with respect to development of the Licensed Assets;
- Selecting and overseeing clinical research organizations, manufacturers and other third party vendors undertaking development work with respect to the Licensed Assets; and
- Making decisions on whether to cease or progress development of a Licensed Asset.

In addition to the development activities above, the following activities represent the most significant commercialization activities that will apply to any Licensed Asset that receives marketing approval. The Company controls all significant decisions with respect to commercialization of the Licensed Assets including the following:

- Sales and distribution of the Licensed Assets;
- Securing commercial supply of the Licensed Assets;
- Activities related to obtaining reimbursement from payors;
- Promotion, advertising and other marketing activities;
- Establishment of a sales force;
- · Performing market research and health economic studies;
- · Conducting post-marketing studies not required to obtain marketing approval;
- · Adverse event reporting; and
- Monitoring sales and medical affairs.

There are no significant development and commercialization decisions with respect to the Licensed Assets that are [**].

In concluding that research and development and commercialization of the Licensed Assets are the activities that most significantly impact Parion's economic performance, the Company determined that (i) the [**] in Parion's pipeline and that, when combined with the anticipated benefits from the development activities contemplated by the Agreement, the Licensed Assets represented (and continue to represent) [**], (ii) there are [**] and (iii) there is a likelihood that Parion's [**]. These factors support the Company's conclusion that there [**] and that Parion is designed so that [**]. Parion has devoted a [**] and has devoted [**]. For example, [**] since entering into the Agreement in June 2015 have been related to its activities under the Agreement. In addition, as of June 30, 2016 [**].[**].

As noted above, the Company acknowledges that there are certain other significant activities of Parion for which the Company does not control decision making. As previously stated, the Company did not acquire any rights to Parion's research and development programs not comprising the Licensed Assets (i.e., P-321 and the tPAD system) and therefore does not have any rights and does not participate in the decisions with respect to the activities Parion undertakes in these areas or in the decisions of Parion as an entity, including whether to seek outside capital or a collaborator to develop P-321 and the tPAD system or any other early-stage research program. For example, the Company acknowledges that it has no control over Parion's use of the \$80 million upfront payment paid to Parion [**] and that Parion could use these funds to develop its other research and development programs, including P-321 and the tPAD system.

Notwithstanding the forgoing, the Company determined that the above activities are not the significant activities that most impact Parion's economic performance for the following reasons:

- [**].
- [**].
- The Company believes that the payments made to Parion to date are [**].

Therefore, the Company believes that although the research and development of P-321 and the tPAD system and the operational and financial decisions of Parion as an entity are significant activities of Parion, [**]. As a result, the research, development, and commercialization the Licensed Assets represent the activities of Parion that are expected to most significantly impact its economic performance.

The Company also acknowledges that Parion, as a result of being a Delaware corporation, has an indefinite life as a matter of law. However, notwithstanding the legal existence of the entity, the Company believes that if Parion's research and development programs, including the Licensed Assets, prove to be unsuccessful, its survival would be limited to a legal technicality, but that the purpose that Parion was designed to create would be extinguished. [**], Parion entered into the Agreement with the Company in order to avoid this very scenario. While Parion has an indefinite life as a matter of law, it could also just as easily liquidate its assets and dissolve. Lastly, since the purpose and design of Parion is to [**], upon expiration of the patents covering the Licensed Assets, the Company would have received the significant majority of its residual returns and the purpose of the entity will have been substantially completed. Therefore, while the Company considered the indefinite life is determinative to the analysis.

Lastly, and as stated in the Company's response letters dated May 27, 2016 and August 12, 2016, the Company reviewed Parion's other research and development programs as part of its overall analysis, including P-321, an ophthalmology candidate which is being developed by Parion for the treatment of dry eye disease, [**]. This is supported by the transaction announced in the January 19, 2016 press release, [**], as compared to the \$80 million upfront payment it received under the Agreement. The May 2, 2016 press release announced Parion's plans to release safety, tolerability and pharmacokinetics data from an early-stage clinical trial of P-321. While this represents development progress of a non-Licensed Asset, [**]. Therefore, the Company does not believe that Parion's activities undertaken with respect to its ophthalmology program or that are described in the January 19, 2016 and May 2, 2016 press releases have a significant effect on the Company's conclusion that the Licensed Assets represent the activities of Parion that are expected to most significantly impact its economic performance.

In summary, a [**] the Licensed Assets over which the Company retains the ultimate decision making authority (i.e., development) or controls decision making (i.e., commercialization). Therefore, the Company believes that

since it has the power to direct the activities that most significantly impact Parion's economic performance that it is the primary beneficiary. Lastly, as required by ASC 810-10-35-4, the Company has and will continue to conduct quarterly assessments of whether the Company remains the primary beneficiary of Parion and has and will monitor the status of P-321 as part of those assessments.

The Company respectfully requests that the information contained in the above response that have been marked [**] be treated as confidential information and that the Commission provide timely notice to Michael J. LaCascia, the Company's Senior Vice President and General Counsel, 50 Northern Avenue, Boston, Ma 02210, (617) 961-7018, before it permits any disclosure of the information in the above response.

Comment 4

We note from your response to comment 4 within your August 12 letter that the key development and commercialization decision with respect to the Licensed Assets are controlled by the Company. Please clarify which activities of Parion you believe most significantly impact Parion's economic performance.

Response 4

As previously stated in the Response Letters, the Company concluded that the research, development and potential commercialization activities associated with the Licensed Assets represent the activities that are expected to most significantly impact Parion's economic performance. For a more detailed description of these activities, please refer to the Company's response to Comment #3.

Comment 5

We note ASC paragraph 805-30-30-1 states that goodwill in a business combination not achieved in stages is initially measured as the excess the consideration transferred (generally measured at acquisition date fair value) plus the fair value of any noncontrolling interest in the acquire over the net of the acquisition-date amounts of the identifiable assets acquired and liabilities assumed measured in accordance with Topic 805. Please clarify for us your calculation of goodwill (including the fair value of any noncontrolling interest) for the acquisition of Parion, and revise your disclosures as appropriate.

Response 5

The Company determined the fair value of the consideration paid to Parion and the fair value of the net assets attributable to noncontrolling interest in connection with accounting for the Agreement as the acquisition of a business pursuant to ASC 805. The Company determined that the fair value of the consideration transferred was \$255.3 million as of June 4, 2015, which consisted of (i) the \$80.0 million up-front payment to Parion, (ii) the estimated fair value of the contingent research and development milestones potentially payable by the Company to Parion and (iii) the estimated fair value of potential royalty payments payable by the Company to Parion.

The Company determined that the fair value of the net assets attributable to noncontrolling interest was \$164.3 million as of June 4, 2015, which represented the Company's estimate of the price a buyer would be willing to pay to acquire Parion's residual interest (Parion's equity) in an orderly transaction between market participants on the measurement date. The Company recorded Parion's assets and liabilities on its balance sheet as of the date of the Agreement, including (a) the fair value of the intangible assets (the Licensed Assets), (b) the fair value of the net assets attributable to noncontrolling interest, and (c) a deferred tax liability resulting from a basis difference in the

intangible assets and certain other net liabilities held by Parion. The difference between the fair value of the consideration paid and the fair value of Parion's net assets (assets less liabilities) was recorded as goodwill as indicated in the table below:

	(in millions)
Intangible Assets	\$255.3
Noncontrolling interest	\$(164.30)
Deferred tax liability	\$(91.00)
Other liabilities	\$(10.50)
Goodwill	\$10.5

The Company will revise its disclosures in the notes to the financial statements in subsequent disclosures with the Commission by including the above table to clarify the residual calculation of goodwill for the acquisition of Parion.



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The Company acknowledges that:

- 1) the Company is responsible for the adequacy and accuracy of the disclosure in its filings;
- 2) Staff comments or changes to disclosure in response to Staff comments do not foreclose the Commission from taking any action with respect to its filings; and
- 3) 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.

Please contact me at (617) 961-5171 or Caroline Wishart at (617) 341-6864 if you have any questions or concerns with respect to this matter.

Very truly yours,

/s/ Paul Silva

Paul Silva

Senior Vice President and Corporate Controller (Principal Accounting Officer)