



VERTEX PHARMACEUTICALS INCORPORATED

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50 NORTHERN AVENUE • BOSTON, MA 02210-1862

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TEL. 617-341-6100 • <http://www.vrtx.com>

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**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**

**(617) 961-7018**

August 12, 2016

**Delivered via EDGAR**

Securities and Exchange Commission  
Division of Corporation Finance  
100 First Street, N.E.  
Mail Stop 4720  
Washington, DC 20549

**Attn: Jim B. Rosenberg, Senior Assistant Chief Accountant**

**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 “Staff”) of the Securities and Exchange Commission (the “Commission”) to Vertex Pharmaceuticals Incorporated (the “Company”) set forth in the Staff’s letter to Jeffrey M. Leiden, dated June 30, 2016 (the “Comment Letter”), 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**

We note from your response your analysis of ASC 810-10-15-17(d) related to scope exceptions. Please describe to us Parion’s capital structure, governance structure and operations prior to the license agreement with you and the changes to them brought about by the license agreement. Include in your response a

description of the activities of Parion that will not be covered under the license agreement and demonstrate to us that the activities of Parion related to you represents substantially all of the activities of Parion.

## Response 1

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

In June 2015, the Company entered into a strategic collaboration and license agreement (the "Agreement") with Parion Sciences, Inc., a privately-held Delaware corporation ("Parion"), pursuant to which the Company received a license to 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 (the "Licensed Assets"). Immediately prior to execution of the Agreement, Parion's research and development efforts were primarily focused on the Licensed Assets and Parion was devoting minimal resources to its other research and development programs, including P-321, which is being developed by Parion for the treatment of dry eye disease, and Parion's trans-nasal pulmonary aerosol delivery ("PAD") system, which is being developed by Parion for use in the treatment of cystic fibrosis and chronic obstructive pulmonary disease. All significant activities of Parion, including research and development of the Licensed Assets, were directed by Parion's board of directors and equity holders. Parion's outstanding equity before and after the Agreement was comprised entirely of common stock. The Company did not acquire an equity interest in Parion or a seat on Parion's board of directors in connection with the Agreement. Accordingly, the capital structure of Parion was not modified in connection with the Agreement.

As set forth in the Company's response letter dated May 27, 2016 (the "Response Letter"), the Company determined that the governance and operations of Parion were significantly revised upon execution of the Agreement since Parion ceded control to the Company over the research, development and commercialization of the Licensed Assets, [\*\*]. As a result, the governance of Parion changed significantly since, following execution of the Agreement, the Company controlled decision-making with respect to the Licensed Assets, as discussed further in the Company's response to Comment 3 below. In supporting its conclusion, the Company considered the redesign of the entity, including the ownership of variable interests and the nature of the entity's activities. Therefore, since the governance and variable interests in Parion were changed, this was considered a redesign of the entity.

The Company concluded that it had participated in the redesign of the operation of Parion's business (as provided in ASC 810-10-15-17(d)(1)) and that Parion was redesigned so that substantially all of its activities either involved or were conducted on behalf of the Company (as provided in ASC 810-10-15-17(d)(2)). In supporting its conclusion, the Company determined that the purpose and redesign of Parion was to advance the development and commercialization of the Licensed Assets with a company that is able to effectively develop and commercialize products for the treatment of cystic fibrosis and other pulmonary diseases. The Company considered the following when it determined that substantially all of Parion's activities either involved or were conducted on behalf of the Company:

- The right to develop and commercialize the Licensed Assets, [\*\*], was obtained by the Company in connection with the Agreement;
- [\*\*]; and
- The Company controls decision making with respect to the research, development and potential commercialization of the Licensed Assets.

The Company's determination that the purpose and design of Parion had been significantly revised as a result of the Agreement and as a result, while Parion is a business, it does not meet the business scope exception in ASC 810-10-15-17(d) since:

- The Company participated significantly in the redesign of Parion. [\*\*]
- [\*\*]; and
- The Company's upfront payment and the related fair value of the contingent consideration [\*\*].

Based on the above considerations, the Company does not believe that the business scope exception to the variable interest model described in ASC 810-10-15-17(d) is applicable.

**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

We note from your response that you determined that you had a variable interest in the licensed assets. Please tell us how you considered the guidance in ASC 810-10-55-32 that states that assets held by a VIE almost always create variability and, thus, are not variable interests. In addition, tell us why the license agreement would not represent a variable interest of you as the licensee held by the licensor, whereby the license agreement would absorb, in part, your variability from development and commercialization of the licensed assets.

## Response 2

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

When identifying variable interests, the Company first considered the variability that Parion was designed to create and distribute and then which interests absorb the variability that Parion was designed to distribute. As described above, the purpose and redesign of Parion was to advance the development and commercialization of the Licensed Assets with a company that is able to effectively develop and commercialize products for the treatment of cystic fibrosis and other pulmonary diseases. The Company determined that it had a variable interest in Parion based upon the Company obtaining a license for the exclusive worldwide rights to the Licensed Assets under the Agreement (the "License") over the patent life of the Licensed Assets.

The License is a contractual arrangement created by Parion to expose its interest holders to increases and/or decreases in the fair value of the Licensed Assets. The License is a variable interest since it will (i) absorb potential losses in the fair value of the Licensed Assets if further development does not support commercialization of the Licensed Assets and (ii) receive potential residual returns from the Licensed Assets if further development supports commercialization. As a result, the fair value of the License fluctuates in parallel with the development progress of the Licensed Assets. As set forth in the Response Letter and in the Company's response to Comment #1 above, since the Company concluded that more than half of the total fair value of Parion was related to the Licensed Assets [\*\*], the Company also determined that the

License represented a variable interest in Parion as a whole, rather than to specified assets in Parion (in accordance with ASC 810-10-25-55).

In addition, the Company considered and determined that Parion did not have a variable interest in the Company since it does not hold an interest that absorbs the variability that the Company was designated to distribute.

**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 3

We note your reference to section 3.6 of the license agreement with Parion as the source of ultimate decision making authority with respect to the licensed assets. Please describe to us the joint steering committee's authority and composition and why you believe you have ultimate decision making authority. In addition, please describe for us the reasons and significance for any activities under the license agreement that are governed differently.

### Response 3

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

The Joint Steering Committee (the "JSC") was established under Section 3.6 of the Agreement and is composed of an equal number of representatives of the Company and Parion. The Agreement provides that the chair of the JSC is a representative of the Company. The JSC is responsible for overseeing activities under the Agreement that cover the most significant decisions with respect to the research and development of the Licensed Assets, including, among other things, reviewing and approving (i) changes to the development plan for the collaboration and associated budgets, (ii) clinical trial protocols, (iii) the progress of development of the licensed compounds and (iv) the decision on whether to proceed with or cease development of the Licensed Assets (see Section 3.6.2).

As set forth in the Response Letter, the Company obtained ultimate decision making authority with respect to the research and development of the Licensed Assets [\*\*]. No significant decisions related to the research and development of the Licensed Assets are governed differently.

The JSC does not have jurisdiction over the commercialization of Licensed Assets that obtain marketing approval. Instead, this contractual right is held exclusively by the Company (see Section 4.1) as Parion has ceded control over all commercialization activities, including manufacturing, marketing and distribution activities. The Company therefore concluded that the Company also controlled commercialization of the Licensed Assets. There are no additional significant activities related to the Licensed Assets that are not governed by the JSC or that are not under the exclusive control of the Company.

In summary, the Company's conclusion that ultimate decision making authority with respect to the research, development and commercialization of the Licensed Assets is held by the Company is based upon (i) [\*\*] and (ii) the Company's contractual right to control commercialization decisions with respect to Licensed Assets that obtain marketing approval.

**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 that you concluded that Parion's equity holders lack the power to direct the activities that most significantly impact Parion's economic performance, as the power to direct Parion's most valuable development program is held by you. Please describe to us the following:

- a. The activities of Parion that most significantly impact its economic performance.
- b. How decisions are made regarding each of those activities.
- c. How you considered any limitations to your power over Parion's activities, which for example, may arise from your power only covering a particular set of activities or the term of the license agreement.
- d. How you expect the significant activities to shift over the life cycle of Parion.

#### **Response 4**

##### **Confidential Treatment Requested by Vertex Pharmaceuticals Incorporated pursuant to Rule 83, Request #4**

###### *Part A*

As set forth in the Company's response to Comment #2 above, the purpose and redesign of Parion was to advance the development and commercialization of the Licensed Assets with a company that is able to effectively develop and commercialize products for the treatment of cystic fibrosis and other pulmonary diseases. The Company concluded that (i) [\*\*]. As a result, [\*\*] (as described in the Company's response to Comment #3 above).

###### *Part B*

As set forth in the Company's response to Comment #3 above, the JSC is responsible for overseeing research and development activities of the Licensed Assets. [\*\*] If research and development activities are successful and the Licensed Assets obtain marketing approval from regulatory agencies, the Company has the exclusive right to commercialize the Licensed Assets. As a result, the Company determined [\*\*] with respect to the Licensed Assets are controlled by the Company.

*Part C*

As set forth in the Company's response to Comment #2 above, the purpose and redesign of Parion was to advance the development and commercialization of the Licensed Assets with a company that is able to effectively develop and commercialize products for the treatment of cystic fibrosis and other pulmonary diseases. As previously stated, the Company concluded [\*\*]. [\*\*] as described in the Company's response to Comment #3. Parion's other research and development [\*\*]. The Company considered any potential limitations of power when assessing 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)."

As a result of the Company's [\*\*] and contractual right to control decision making with respect to commercialization as discussed in the Company's response to Comment #3 above, the Company retains ultimate decision making authority with respect to the research, development and commercialization of the Licensed Assets throughout the term of the Agreement.

*Part D*

The purpose and redesign of Parion was to advance the development and commercialization of the Licensed Assets with a company that is able to effectively develop and commercialize products for the treatment of cystic fibrosis and other pulmonary diseases. As previously stated, [\*\*].

Research and development of drug candidates is subject to numerous risks and uncertainties and it is difficult to predict whether any of Parion's programs will progress or what direction Parion may move in the future. Nonetheless, as discussed in the response to Part C above, the Company controls decision making throughout the development and commercialization phases of the Licensed Assets.

**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 5**

Please tell us whether decision-making rights change should Parion opt for the co-development election, as described in section 3.2.6. of the license agreement.

**Response 5**

**Confidential Treatment Requested by Vertex Pharmaceuticals Incorporated pursuant to Rule 83, Request #5**

Section 3.2.6 of the Agreement provides, in certain circumstances, Parion with the right to co-develop and co-commercialize (the “Co-development Right”) with the Company specified licensed compounds for two specific indications: the treatment of non-CF bronchiectasis and chronic obstructive pulmonary disease. The Co-development Right does not apply to (i) P-1037, the most advanced compound licensed by the Company which was and continues to be in Phase 2 clinical development or (ii) development of any Licensed Asset as a treatment for cystic fibrosis, [\*\*].

**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 6**

Please explain to us why the \$255,340,000 consideration paid to Parion differs from the \$164,317,000 net assets attributable to noncontrolling interest. In addition, tell us how you attribute interests in Parion to noncontrolling interest.

#### **Response 6**

##### **Confidential Treatment Requested by Vertex Pharmaceuticals Incorporated pursuant to Rule 83, Request #6**

The Company considered ASC 810-10-30-2 when determining that the initial consolidation of Parion should be accounted for in accordance with the provisions in ASC Topic 805. Therefore, the Company measured the consideration transferred to Parion and the valuation of the noncontrolling interest at fair value.

ASC 810-10 defines the noncontrolling interest in an entity as the portion of the equity (net assets) in a subsidiary (in this case, Parion) not attributable, directly or indirectly, to a parent (in this case, the Company). Since the Company did not acquire an equity interest in Parion, 100% of Parion’s equity (net assets) is attributed to Parion’s shareholders. The Company determined that the fair value of the net assets attributable to noncontrolling interest was \$164.3 million, 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. The Company determined that the fair value of Parion’s equity should be estimated based on (i) the \$80.0 million up-front payment to Parion, *plus* (ii) the estimated fair value of contingent payments (milestones and royalties) payable by the Company to Parion, which was determined after considering the probability and estimated timing of such payments and an appropriate discount rate, *less* (iii) Parion’s tax liability associated with the receipt of such payments at Parion’s effective tax rate. [\*\*]

In summary, while the underlying contractual payments, probabilities and estimated timing of payments used to determine the fair value of the consideration transferred and the fair value of the noncontrolling interest are the same, the primary difference in the measurement of the consideration transferred and the fair value of the noncontrolling interest is that the fair value of the noncontrolling interest includes Parion’s estimated tax liability with respect to the upfront and contingent payments from the Company. As such, the \$164,317,000 net assets attributable to noncontrolling interest represents the value of Parion’s cash flows to its stockholders.

As stated above, the Company did not acquire an equity interest in Parion. As such, the noncontrolling interest represents 100% of Parion's equity, and therefore, the Company attributes all interests in Parion to noncontrolling interest.

**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.**

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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)