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# **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
	Lisa Vanjoske, Assistant Chief Accountant
	James Peklenk, Staff Accountant

Re: Vertex Pharmaceuticals Incorporated Form 10-K for the Fiscal Year Ended December 31, 2011 Filed February 22, 2012 Form 10-Q for the Quarterly Period Ended March 31, 2012 Filed May 10, 2012 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 Ian F. Smith dated August 20, 2012 (the "<u>Comment Letter</u>") regarding the Company's filings with the Commission referenced above. The Comment Letter was issued in response to the Company's letter to the Commission dated July 11, 2012 responding to the Staff's original comment letter dated June 26, 2012. The comments from the Comment Letter are reproduced below together with the Company's responses to those comments.

#### Comment 1

Refer to your response to our comments two and five. Please tell us how you considered the guidance in ASC 730-10-15-4 a. through e. in determining that classifying the drug supply costs incurred prior to 2011 totaling \$203.8 million as research and development expenses in your statements of operations complies with GAAP.

#### **Response 1**

The Company's drug supply costs incurred prior to 2011 for telaprevir (an hepatitis C virus ("<u>HCV</u>") protease inhibitor, which the Company markets under the brand name INCIVEK<sup>TM</sup> for the treatment of patients with genotype 1 HCV infection) are set forth below. These drug supply costs

consisted of (i) commercial drug supply costs including (a) raw materials and manufacturing costs, (b) costs incurred by the Company to establish the thirdparty infrastructure required to manufacture telaprevir and (c) costs of validating these third-party manufacturers' systems, and (ii) costs for manufacturing services provided to the Company's telaprevir research and development collaborators, Janssen Pharmaceutica, N.V. ("Janssen") and Mitsubishi Tanabe Pharma Corporation ("<u>Mitsubishi</u>").

		2006- 2008		2009 (in thousands)		2010		Total for period prior to 2011
INCIVEK (telaprevir) drug supply costs:				,	,			
Commercial drug supply costs:								
Raw materials and manufacturing costs		42,387	\$	10,849	\$	38,975	\$	92,211
Third-party manufacturing infrastructure costs		18,374		1,503		772		20,649
Third-party validation expenses		31,061		1,872		592		33,525
Total commercial drug supply costs		91,822		14,224		40,339		146,385
Manufacturing services (collaborator supply)		28,350		6,170		22,922		57,442
Total INCIVEK drug supply costs		120,172	\$	20,394	\$	63,261	\$	203,827

In determining to classify all of these drug supply costs as research and development expenses, the Company considered the guidance in ASC 730 "Research and Development," including as described below the guidance in ASC 730-10-15-4 a. through e. (which requires that the costs of certain transactions and activities be excluded from research and development expenses).

## Commercial Drug Supply Costs

- (i) The Company's commercial drug supply costs include costs of purchasing raw materials; manufacturing costs incurred to convert these raw materials into active pharmaceutical ingredient ("<u>API</u>") and finished goods; and costs incurred to establish the Company's supply chain, which the Company was required to design, test and validate in order to obtain approval for INCIVEK (telaprevir) from the United States Food and Drug Administration (the "<u>FDA</u>"). These commercial drug supply costs did not include any costs of research and development activities conducted for others under contractual arrangements, which would be excluded from research and development expenses pursuant to ASC 730-10-15-4 a.
- (ii) ASC 730-10-15-4 b. does not apply to the Company's commercial drug supply costs because this guidance applies solely to the costs of activities that are unique to companies in extractive industries.
- (iii) The Company's commercial drug supply costs did not include any costs related to the acquisition, development or improvement by the Company of processes for use in selling activities or administrative activities that would be excluded from research and development expenses pursuant to ASC 730-10-15-4 c.
- (iv) ASC 730-10-15-4 d. excludes from research and development expenses costs of routine or periodic alterations to existing products, production lines and manufacturing processes. The Company evaluated the activities related to its commercial drug supply costs incurred prior to 2011, including activities related to the design, testing and validation of the INCIVEK production lines and manufacturing processes, and determined that none of the costs related to

2

these activities should be excluded from research and development expenses pursuant to ASC 730-10-15-4 d. because (a) INCIVEK was not yet a marketed product (as it was not approved by the FDA until May 23, 2011) and (b) none of the activities related to the manufacturing processes were routine or periodic alterations, because they remained subject to FDA review and approval until May 23, 2011.

(v) The Company's commercial drug supply costs did not include any costs for market research or market testing activities that would be excluded from research and development expenses pursuant to ASC 730-10-15-4 e.

# Manufacturing Services (Collaborator Supply)

(i) The Company applied ASC 808-10-15 to its research and development arrangements with Janssen and Mitsubishi and determined that they are properly classified as collaborative arrangements. The Company conducted research and development activities related to the development of telaprevir, including the evaluation of telaprevir in multiple clinical trials and the development of the commercial manufacturing process and supply chain for telaprevir, pursuant to contracts providing for the Company's collaborations with Janssen and Mitsubishi. Under the Company's collaborative telaprevir arrangements, (1) the Company led the clinical development program for telaprevir, (2) the parties shared responsibility and costs for conducting research and development activities, (3) the Company licensed to its collaborators the rights to manufacture and commercialize telaprevir in their territories in return for royalties and/or milestone payments and (4) the Company retained the exclusive right to manufacture and commercialize telaprevir in North America. These activities included (a) the design and validation of the Company's third-party manufacturing network and (b) arranging for the Company's third-party contract manufacturers to supply Janssen with raw materials and Mitsubishi with work-in-process. These raw materials and work-in-process were necessary to support the clinical trials of telaprevir conducted by Janssen and Mitsubishi and the initial commercial launch of telaprevir by Janssen and Mitsubishi during the period in which they were each establishing their independent manufacturing supply chain for telaprevir in their respective territories. The expenses related to supplying the Company's collaborators are reflected in the above table under the caption "Manufacturing services (collaborator supply)."

In applying the guidance in ASC 808-10-15, the Company concluded that its arrangements with Janssen and Mitsubishi were collaborative arrangements because (A) each of the parties was actively participating in the collaboration and (B) the parties shared in significant risks and rewards that were dependent on the successful development of telaprevir. Accordingly, the Company determined that its telaprevir research and development expenses were costs incurred in connection with collaborative arrangements in which the Company retained significant potential benefits and that, conversely, ASC 730-10-15-4 a., which applies to costs of research and development activities conducted for others under a contractual arrangement, did not apply.

(ii) ASC 730-10-15-4 b. did not apply to the Company's manufacturing services (collaborator supply) costs because this guidance applies solely to the costs of activities that are unique to companies in extractive industries.

3

- (iii) The Company's manufacturing services (collaborator supply) costs did not include any costs related to the acquisition, development or improvement by the Company of processes for use in selling activities or administrative activities that would be excluded from research and development expenses pursuant to ASC 730-10-15-4 c.
- (iv) The Company's manufacturing services (collaborator supply) costs did not include any costs related to routine or periodic alterations to existing products, production lines or manufacturing processes that would be excluded from research and development expenses pursuant to ASC 730-10-15-4 d.
- (v) The Company's manufacturing services (collaborator supply) costs did not include any costs for market research or market testing activities that would be excluded from research and development expenses pursuant to ASC 730-10-15-4 e.

Accordingly, the Company reflected all of the INCIVEK drug supply costs incurred prior to 2011 as research and development expenses.

Refer to your response to our comment three. In your response you state that, as of January 1, 2011, you had expensed, in periods prior to 2011, \$84 million in INCIVEK inventory which you refer to as "Zero Cost Inventory". You state that these Inventory costs were charged to R&D expense in your Statements of Operations for periods prior to 2011 because you had not received FDA approval to commercialize INCIVEK until May 2011. Further you state that this inventory is to be sold to your customers when they reach the finished goods stage and that the future Revenue from Product Sales of this \$84 million in "Zero Cost Inventory" approximates \$1.8 billion. Finally you stated that this inventory should be sold by the end of 2013 although your table on page 6 indicates that there would still be \$10 million in inventory at December 31, 2013. We have the following additional comments:

- To the extent that costs included in the \$84 million are not part of the drug supply costs referred to in comment one above, tell us how you considered the guidance in ASC 730-10-15-4 a. through e. in determining that classifying these costs incurred prior to 2011 as research and development expenses in your statements of operations complies with GAAP.
- Tell us why a material portion of the \$112.4 million and \$126.9 million Inventory at December 31, 2011 and March 31, 2012 should not be classified as "non-current" assets since your accounting is on a FIFO basis and you estimate that you will still have over \$10 million of "Zero Cost Inventory" unsold at December 31, 2013.
- Tell us what the shelf life is for INCIVEK and why you believe you will be able to realize inventory held at December 31, 2011, March 31, 2012 and June 30, 2012.

#### **Response 2**

- The entire \$84 million in Zero Cost Inventory is included in the commercial drug supply costs referred to in comment one above.
- The \$10 million in Zero Cost Inventory that the Company estimated would remain unsold at December 31, 2013 represented the costs of the final raw materials that the Company purchased

4

prior to 2011, which it expected would be converted into finished goods and sold after December 31, 2013. Even though the Company uses FIFO, the Company expected that a significant portion of the inventories reflected on the Company's balance sheets as of December 31, 2011 and March 31, 2012 would be realized prior to the date that the Company realized the final portion of the Zero Cost Inventory. This is due to the costs incurred after January 1, 2011 (to advance raw materials and work-in-process that were previously expensed through the supply chain and to convert them into finished goods) that are capitalized as part of inventories and then expensed as cost of product revenues when the finished goods are sold.

The INCIVEK manufacturing process requires a minimum period of 18 months from the placement of orders for raw materials until the production of finished goods, which is similar to the lead times required to manufacture other pharmaceutical products. The Company manages its inventories in order to mitigate the risk of potential product shortages that could result from increases in demand, risks of disruptions at manufacturing facilities and the potential for product quality issues. During the quarters ended December 31, 2011 and March 31, 2012, the Company continued to build additional INCIVEK inventories due to the higher than expected demand for INCIVEK in the initial launch period and the forecasted demand for INCIVEK (the Company would later reduce its expectations regarding future INCIVEK demand based on the factors discussed in detail below in response to comment three). Applying the guidance in ASC 210-10-20 and ASC 210-10-45-1 and consistent with the classification of inventories to be consumed through commercial sale and none of these inventories were subject to any contractual or labeling restrictions.

INCIVEK tablets (which correspond to the Company's finished goods inventories) have a shelf life of two years. The API in INCIVEK has a shelf life of approximately six years (including initial conversion into an intermediate form, which must be done within four years, and the conversion of the intermediate form into INCIVEK tablets, which must be done within two years). Raw materials do not have a specified shelf-life, but the Company has stability data indicating that they can be stored for several years prior to conversion into API.

In order to estimate whether it will be able to realize its inventories, the Company evaluates inventories at each stage of the supply chain, taking into account the conversion process and timing as well as the shelf life of the inventories at each stage in the process, and comparing the available inventories with the Company's expectations regarding future demand for INCIVEK. This analysis requires the Company to make significant estimates and judgments. As of December 31, 2011 and March 31, 2012, the Company estimated that all of its inventories would be realizable.

As described in greater detail in response to comment three below, in the second quarter of 2012, the Company recorded a lower of cost or market charge relating to excess and obsolete inventories following an adverse change in the Company's commercial outlook for INCIVEK and expectations of decreased demand. At June 30, 2012, based on the Company's analysis of inventories at each stage in the Company's supply chain and its revised commercial outlook for INCIVEK, the Company (a) impaired a significant portion of raw materials and work-in-process inventories that the Company no longer estimated would be realized, but (b) did not impair any finished goods because it continued to expect to sell all of the INCIVEK finished goods prior to

the expiration of the two-year shelf life for these tablets. The raw materials and work-in-process that were impaired as of June 30, 2012 included raw materials and work-in-process that the Company had estimated as of December 31, 2011 and March 31, 2012 would be realizable, based on earlier projections of the future demand for INCIVEK. Following the \$78.0 million lower of cost or market charge recorded in the second quarter of 2012 and, as discussed in the Company's response to comment three below, the Company estimated that all of the INCIVEK inventories reported on the Company's condensed consolidated balance sheet as of June 30, 2012 were realizable.

## **Comment 3**

We have the following comments regarding the \$78 million reserve you recorded for the quarterly period ended June 30, 2012 "to reserve against the potential for excess INCIVEK inventory":

<sup>5</sup> 

- Tell us how you considered the guidance in ASC 330-10-50-2 which indicates that it would be desirable to separately identify the \$78 million charge in your statement of operations.
- Please clarify what is meant by "reserve against the potential for excess INCIVEK inventory" to indicate whether and, if so, to what extent it
  refers to the carrying value of inventory or to expected future sales returns under your policy of allowing products to be returned up to
  twelve months after the labeled expiration date.
- Tell us if you believe there is excess inventory in your distribution channel and whether you expect to incur a material increase in INCIVEK product returns.
- Describe the events and timeline leading to your decision to record the \$78 million reserve in the quarter ended June 30, 2012.
- Provide us analyses demonstrating why a similar charge was not necessary at either December 31, 2011 and/or at March 31, 2012. In your response, tell us the facts and circumstances that existed before issuing the financial statements for those dates that supported your assertion that inventory amounts reflected on the December 31, 2011 and March 31, 2012 balance sheets were stated at lower of cost or market. In doing so, please address your statement in the April 26, 2012 "Earnings Call" that INCIVEK Revenues of \$357 million, down from \$456.8 million in the 4<sup>th</sup> Quarter of 2011, were "affected by a reduction of approximately \$22 million in inventory levels by wholesalers between December 31, 2011, and March 31, 2012."

#### **Response 3**

The Company considered the guidance in ASC 330-10-50-2, which indicates that it will frequently be desirable to disclose separately the amount of a lower of cost or market charge from the cost of consumed inventory, when it prepared the disclosure contained in its Quarterly Report on Form 10-Q for the period ended June 30, 2012. After reviewing the guidance in ASC 330-10-50-2, the Company determined that, while it was not necessary to include a separate line in its condensed consolidated statements of operations in order to separately disclose the amount of the charge from the cost of consumed inventory, the Company should prominently disclose the charge and provide detailed disclosure that clearly distinguished the amount of the charge from the cost of consumed inventory. On the face of the Company's condensed consolidated statements of operations, the Company included a

6

reference to Note H next to "Cost of product revenues" that directed readers to the detailed discussion of the \$78.0 million charge contained in the notes accompanying the condensed consolidated financial statements. The Company (i) specifically disclosed the \$78.0 million charge in the second paragraph of its "Management's Discussion and Analysis of Financial Condition and Results of Operations," (ii) provided a more detailed discussion of the \$78.0 million charge later in the same section under the caption "Drug Supply and INCIVEK Inventory Write-down," and (iii) separately identified the \$78.0 million charge in its discussions of "Net income (loss) attributable to Vertex" and "Cost of product revenues."

- The reserve against the potential for excess INCIVEK inventories refers solely to the carrying value of inventories owned by the Company prior to the sale of INCIVEK to the Company's distributors. This reserve does not include any amounts for expected future sales returns under the Company's policy of allowing INCIVEK to be returned beginning six months before and ending up to twelve months after the labeled expiration date. As of June 30, 2012, the Company's distributors held less than three weeks of INCIVEK channel inventory. All of this channel inventory was sold by the distributors prior to the filing of the Company's Quarterly Report on Form 10-Q for the period ended June 30, 2012.
- The Company does not believe there is excess inventory in its distribution channel, nor does the Company expect any material increase in INCIVEK product returns. The Company has evaluated the inventory in its distribution channel and has determined that during the past 12 months, the Company's distributors have maintained on average less than three weeks of INCIVEK inventory in the distribution channel. These levels of inventory in the distribution channel are consistent with the requirements in the contracts between the Company and its distributors, which are intended to limit the amount of INCIVEK distribution channel inventory. The Company receives reports on a weekly basis from distributors (including weekly reporting of distributors' sales and channel inventory levels) and from IMS Health (a third party that tracks prescriptions from healthcare providers). These reports provide the Company with visibility into the amount of inventory held in the distribution channel and the number of prescriptions that have been given to patients, and allow the Company to continually estimate the quantities of INCIVEK that are eligible to be returned.
- The \$78.0 million charge related to raw materials and work-in-process that prior to revising its commercial outlook for INCIVEK in July 2012 the Company expected to utilize in future periods. The Company revised its commercial outlook for INCIVEK primarily as a result of information it received in the second quarter of 2012 and July 2012 regarding (i) decreases in INCIVEK prescriptions levels and (ii) positive results from clinical trials being conducted by competitors evaluating potentially competitive HCV treatment regimens.

The field of HCV infection treatment is dynamic, with rapidly and frequently changing expectations regarding the future competitive landscape that make it difficult to predict future demand for INCIVEK. When INCIVEK was approved in May 2011, the Company expected that INCIVEK's launch would be similar to other recent drug launches, with demand for INCIVEK building over the course of the second half of 2011 and peak demand occurring from 2012 through 2014. The Company expected that competitive products would not be approved for several years, and that these products, if approved, would result in significant decreases in demand starting in late 2014. The Company's early expectations regarding the

INCIVEK launch have proven to be incorrect. The Company currently believes, based on information that became available in the second quarter of 2012, that peak demand occurred in the fourth quarter of 2011 and that total future demand is less than previously anticipated. The Company believes that this earlier occurrence of peak demand and the reduction in estimated total demand for INCIVEK is primarily the result of the positive data from mid-stage clinical trials evaluating HCV drug candidates being developed by the Company's competitors and the acceleration of the development timelines for these potentially competitive products. Not only has this information shortened the period during which the Company expects that there will be demand for INCIVEK, but it appears that it has reduced current treatment rates of patients with genotype 1 HCV infection and will continue to reduce these treatment rates in future periods.

The HCV drug candidates being developed by the Company's competitors are subject to the high risks inherent in drug development, have not been evaluated in late-stage clinical trials and may not be approved by the FDA. As a result, the Company exercised significant judgments in order to estimate the affect that these drug candidates will have on future demand for INCIVEK. If the development of several of these drug candidates is delayed or terminated, future demand for INCIVEK could be greater than the Company currently estimates. If the development of competitive products is further accelerated, or the demand for INCIVEK is further eroded by competitive pressures, future demand could be less than the Company currently estimates.

## Timeline and Analysis of Timing of Inventory Charge

In May 2011, the Company obtained approval in the United States for INCIVEK (which is an HCV protease inhibitor), and Merck & Co., Inc. obtained approval for a competitive HCV protease inhibitor marketed under the brand name VICTRELIS<sup>TM</sup>. These two drugs represented the first new drugs approved for the treatment of genotype 1 HCV infection since 2002 and provided improved treatment options for patients with genotype 1 HCV infection. Each of these new drugs is taken in combination with pegylated-interferon (a drug administered through weekly injections) and ribavirin (another oral drug).

2011 revenues from INCIVEK significantly exceeded the Company's original forecasts for the launch, with \$420 million in INCIVEK net revenues in the third quarter of 2011 and \$457 million in INCIVEK net revenues in the fourth quarter of 2011. As a result, during the quarters ended December 31, 2011 and March 31, 2012, the Company continued to build additional INCIVEK inventories. In February 2012, the Company expected that INCIVEK net revenues would be between \$1.5 billion and \$1.7 billion in 2012 and would continue at similar levels until the introduction of competitive products. In February 2012, based on its forecasts at the time, the Company estimated that all of its inventories on hand as of December 31, 2011 would be sold and concluded that the value of its inventories was realizable. This estimate was based on its demand forecasts, which were consistent with its public guidance for 2012, as well as long-range forecasts estimating that INCIVEK demand would not begin to be significantly negatively affected by competition until late 2014.

In April 2012, the Company reiterated its \$1.5 billion to \$1.7 billion guidance for 2012 INCIVEK net revenues based on the information that was available to it at the time. While

8

INCIVEK net revenues had decreased from the fourth quarter of 2011 to the first quarter of 2012, the primary cause of this decrease appeared to be expected seasonality, as fewer patients began treatment with INCIVEK during the holiday season (patients take INCIVEK for three months, filling three separate monthly prescriptions, so a decrease in new patient starts during the 2011 holiday season resulted in lower revenues in January 2012 and February 2012). New patient starts increased in the first quarter of 2012, supporting the Company's expectation that revenues would increase over the remainder of 2012 as compared to the first quarter of 2012. During its April 26, 2012 "Earnings Call," the Company referred to a decrease of \$22 million in distribution channel inventory to indicate that the timing of deliveries to distributors may have contributed to higher fourth quarter 2011 INCIVEK net revenues and lower first quarter 2012 INCIVEK net revenues. The Company did not believe that the decrease in channel inventory was a significant indicator of future demand for INCIVEK. Accordingly, the Company estimated that its INCIVEK inventories as of March 31, 2012 would be sold and concluded that the value of its inventories was realizable.

From April 18, 2012 through April 22, 2012, a major scientific conference (the annual conference of the European Association for the Study of the Liver, or "<u>EASL</u>") was held during which the Company's competitors presented positive results from a number of mid-stage clinical trials evaluating all-oral combination therapies for the treatment of HCV infection. The Company, and its competitors, are seeking to develop all-oral combination therapies for the treatment of HCV infection that could render noncompetitive treatment regimens that include pegylated-interferon. Prior to the 2012 EASL conference, limited data regarding such potential all-oral combination treatments had been published. The positive results presented at the 2012 EASL conference included results from Phase 2 clinical trials of all-oral HCV treatment regimens conducted by the Company's competitors, including Abbott Laboratories, Bristol-Myers Squibb Company and Gilead Sciences, Inc. In addition, at and following this conference, these competitors announced plans for the continued clinical development of their all-oral treatment regimens, including plans for increasing numbers of mid- and late-stage clinical trials of potentially competitive HCV drug candidates.

In late May 2012 (when prescription data regarding late April 2012 and early May 2012 first became available), the Company determined that there had been a significant decline in the number of INCIVEK prescriptions for new patients beginning the week following the 2012 EASL conference. This lower level of new patient starts continued during the remainder of the second quarter of 2012 and the early part of the third quarter of 2012. The Company believes that the decrease in patients seeking treatment is the result of (i) healthcare providers and patients choosing to continue to monitor patients' health instead of initiating treatment immediately, as a result of the clinical data regarding potential alloral treatment regimens and the potential for these new treatments to become commercially available sooner than previously expected, and (ii) patients choosing to enroll in the increased number of mid- and late-stage clinical trials of these new potential treatment regimens rather than seeking treatment with products such as INCIVEK that already have been approved for commercial sale.

In July 2012, the Company re-evaluated its near-term and long-term forecasts for INCIVEK demand, and reduced its estimates regarding demand for INCIVEK as a result of (i) the

recent decreases in demand for INCIVEK and the Company's expectation that demand will decrease further in future periods, (ii) the potential development by the Company and its competitors of other drugs and combination treatments for HCV infection, (iii) positive results released in the second quarter of 2012 from Phase 2 clinical trials of drug candidates being developed by competitors and (iv) the recent initiation by competitors of a number of additional Phase 2 and Phase 3 clinical trials of drug candidates for the treatment of HCV infection. In July 2012, based on these revised estimates, the Company reduced its guidance regarding 2012 INCIVEK net revenues from the original range of \$1.5 billion to \$1.7 billion to new full-year 2012 guidance of \$1.1 billion to \$1.25 billion. The Company's INCIVEK net revenues for the first half of 2012 were approximately \$685 million and, based on the Company's revised guidance, the Company is now projecting that its INCIVEK net revenues will decrease to between \$415 million and \$565 million in the second half of 2012.

The reduction in its guidance for 2012, together with the reduction in the Company's long-term forecasts, resulted in the Company (a) revising its estimates of the INCIVEK inventories that were realizable and (b) recording the \$78.0 million charge in the second quarter of 2012. The Company evaluated each category of inventories separately in connection with determining the amount of this charge. The Company impaired almost all of the INCIVEK raw materials in its inventories and, as of June 30, 2012, carried only \$1.4 million of the INCIVEK raw materials on its condensed consolidated balance sheet. The Company impaired approximately 43% of the INCIVEK work-in-process. The Company did not impair any INCIVEK finished goods because it still expected that all of these finished goods would be sold within the two-year shelf life of the INCIVEK finished goods.

# **Comment 4**

On page 41 of your Form 10-Q for the period ended June 30, 2012, you state "we recorded within cost of product revenues a \$78.0 million charge for excess and obsolete INCIVEK inventories, which included an accrual for estimated expenses related to our non-cancelable purchase commitments." We have the following comments:

- Please name these "non-cancelable" purchase commitments and provide us a description of the key terms and commitments included therein.
- Clarify if they contain mandatory minimum periodic purchases of product and, if so, summarize those commitments and explain why they were not included in your Form 10-K disclosure and Contractual Obligations table.
- · Describe the source, nature and amount of the "accrual for estimated expenses" referred to above.

## **Response 4**

The Company's accrual for estimated expenses related to its "non-cancelable" purchase commitments totaled \$16.0 million of the \$78.0 million charge for excess and obsolete INCIVEK inventories. These purchase commitments referred to six purchase orders with four contract manufacturers for raw materials, API and other materials classified as work-in-

10

process that were scheduled for delivery in the second half of 2012. The purchase orders generally included delivery date, quantity and price, with payment due 30-45 days after invoicing. As of June 30, 2012, substantially all of the manufacturing work associated with these purchase orders was completed and the purchase orders could not be cancelled.

- The Company's agreements with its third-party contract manufacturers do not contain any mandatory periodic purchases of inventories. Two of the Company's agreements with its third-party contract manufacturers contained provisions requiring an aggregate of \$9.5 million in reservation fees to ensure an allocation of production capacity in 2012. These reservation fees were included under the caption research, development and drug supply costs in the contractual commitments and obligations table in the Company's Form 10-K for the year ended December 31, 2011. As of December 31, 2011, the Company had outstanding purchase orders under these contracts that were entered into in the ordinary course of business, some of which were non-cancellable and some of which the Company could cancel but would be obligated to pay for costs incurred through the cancellation date. The non-cancellable amounts were not included in the Company's contractual commitments and obligations table.
  These amounts were not material to the Company's liquidity at December 31, 2011. In future filings, the Company will include non-cancellable amounts pursuant to open purchase orders for raw materials, work-in-process or finished goods in its contractual commitments and obligations table.
- The \$78.0 million charge consisted of (i) a reserve for materials that would have been reflected as inventories on the condensed consolidated balance sheet as of June 30, 2012 if the Company had not recorded the charge for excess and obsolete INCIVEK inventories and (ii) an accrual for materials that the Company had ordered and that were scheduled for delivery in the second half of 2012. The \$16.0 million accrual was for the estimated costs of the materials that were scheduled for delivery in the second half of 2012. In order to estimate this accrual, the Company reviewed its outstanding purchase orders and the invoices it had received from its third-party contract manufacturers.

The Company hereby confirms that in future filings the Company will enhance its overall disclosures by complying with the comments provided by the Commission in the manner set forth in the responses above, subject in all cases to any changes with respect to the facts underlying the Company's disclosures.

In addition, 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 617-444-0878 in the event that you have any questions or concerns with respect to this matter. In the event that I am not available, please contact my colleague, Valerie L. Andrews, Vice President and General Counsel, at 617-444-6227.

Very truly yours,

/s/ Kenneth L. Horton

Kenneth L. Horton Executive Vice President and Chief Legal Officer