PTC Therapeutics, Inc.
100 Corporate Court
South Plainfield, NJ 07080
908.222.7000
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January 21, 2016

FOIA CONFIDENTIAL TREATMENT REQUEST
The entity requesting confidential treatment is:
PTC Therapeutics, Inc.
100 Corporate Court
South Plainfield, NJ 07080
Attn: Shane Kovacs, Executive Vice President, Chief Financial Officer and
Head of Corporate Development
908-222-7000

BY EDGAR:

U.S. Securities and Exchange Commission
Division of Corporation Finance
100 F Street, NE
Mail Stop 4720
Washington, D.C. 20549

Attention: Jim B. Rosenberg

Re: PTC Therapeutics, Inc.
Form 10-K for the Fiscal Year Ended December 31, 2014
Filed March 2, 2015
Form 10-Q for the Quarterly Period Ended September 30, 2015
Filed November 9, 2015
File No. 001-35969

Ladies and Gentlemen:

This letter is submitted on behalf of PTC Therapeutics, Inc. (the "Company") in response to the comments in the letter dated December 15, 2015 (the "Comment Letter") from Jim B. Rosenberg of the staff (the "Staff") of the United States Securities and Exchange Commission (the "Commission") to Shane Kovacs, Chief Financial Officer of the Company, with respect to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2014, as filed with the Commission on March 2, 2015 (the "2014 Form 10-K") and the Company's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2015, as filed with the Commission on November 9, 2015 (the "2015 Third Quarter Form 10-Q"). The Staff's comments are reproduced below in bold in the order in which they were set out in the Comment Letter and the Company's corresponding responses are shown below the applicable comments and numbered accordingly.

Form 10-K for the Fiscal Year Ended December 31, 2014
Item 6. Selected Financial Data, page 94

1. **You present only three years of statements of operations data in your table. As information for 2011 was presented in your initial public offering registration statement on Form S-1, File Number 333-193677, please represent to us that you will include five years of information in your 2015 Form 10-K as required by Item 301(a) of Regulation S- K. In addition, please represent that you will include the balance sheet information required by Instruction 2 to Item 301 of Regulation S-K in your 2015 Form 10-K.**

Response to Comment No. 1

In response to the Staff's comment, the Company confirms that in its Form 10-K for the fiscal year ended December 31, 2015, it will include (i) five years of information in the statement of operations table in Selected Financial Data as required by Item 301(a) of Regulation S- K and (ii) the balance sheet information required by Instruction 2 to Item 301 of Regulation S-K.

Management's Discussion and Analysis of Financial Condition and Results of Operations
Critical accounting policies and significant judgments and estimates
Inventories and Cost of Product Revenues, page 100

2. **Please tell us why you have not capitalized any inventory costs for Translarna product manufactured for sale in Europe under your conditional approval and reference for us the authoritative literature you relied upon to support your accounting. Please ensure your response also addresses the following:**

   - **Tell us the amount of inventory costs you charged to expense in each fiscal year.**
   - **Tell us the amount of inventory costs you charged to expense prior to receipt of conditional approval.**
   - **Tell us why it is appropriate to charge inventory costs incurred after receipt of conditional approval to research and development expenses. Explain to us how the ultimate commercial sale of this product meets the definition of research or development under ASC 730-10-20 by discovering new knowledge or translating that knowledge into new products, processes or techniques.**

- **Tell us the amount of royalties and other miscellaneous selling costs, as indicated on page 10 of your September 30, 2015 Form 10-Q, associated with your product sales that you have charged to research and development costs. Explain to us how these costs meet the definition of research or development.**
- **Tell us the amount of zero-cost inventory you have on hand in terms of units, the number of units you have sold by reporting period through September 30, 2015 and why you do not provide any indication of the amount of this inventory on hand in your filings.**
- **Although you characterize the amount of cost of sales in 2014 as being insignificant, tell us what the cost of sales for 2014 and each quarter in 2015 would have been if you had not charged all your inventory costs to research and development expenses. Tell us your consideration for disclosing these amounts and why it is apparently not meaningful information for investors to understand the potential gross margins for Translarna.**

Response to Comment No. 2

The Company believes it is important to understand its manufacturing process to help evaluate its responses to the Staff's questions above. It typically takes between 18 months and two years to manufacture the Company's Translarna product from start to finish. The manufacturing process includes a series of steps and various third party suppliers to convert the raw materials to the finished drug product. Historically, 100% of finished Translarna drug product was produced for clinical study use and these manufacturing costs were therefore expensed as research and development expenses in accordance with Accounting Standards Codification (ASC) 730-10, Research and Development.

In August 2014, in connection with receiving a positive opinion from the Committee for Medicinal Products for Human Use (CHMP), the European Medicines Agency (EMA) granted conditional marketing authorization for Translarna for the treatment of nonsense mutation Duchenne muscular dystrophy (nmDMD) in the European Economic Area (EEA), which we refer to herein as the conditional marketing authorization. A conditional marketing authorization granted by the EMA is only valid for a one-year period and must be renewed annually by the EMA following a regulatory re-assessment of the risk-benefit balance of the marketing authorization and the need for additional or modified conditions. Prior to receiving the conditional marketing authorization, the manufacturing cost for all Translarna product on hand had been expensed as research and development costs in prior fiscal periods.

Rule 83 Confidential Treatment by PTC Therapeutics, Inc. Request #1

Sales of commercial product during 2014 and 2015 were fulfilled with Translarna product that had completed the manufacturing process and the associated product manufacturing costs had been expensed as research and development costs in fiscal periods prior to receipt of the conditional marketing authorization. Following the receipt of the conditional marketing authorization, the Company incurred finishing costs that include packaging costs and indirect overhead costs that were specific to directing this previously expensed clinical product for use as commercial supply during 2014 and 2015. For the nine months ended September 30, 2015 and for the year ended December 31, 2014, the Company expensed approximately $[**] and $[**], respectively, of aggregate Translarna product manufacturing and finishing costs which included both clinical research directed product and commercial supply. Approximately $[**] and $[**] represent finishing costs that were incurred to direct product to commercial use for the nine months ended September 30, 2015 and for the year ended December 31, 2014, respectively. The Company determined that it was appropriate to classify these product manufacturing and finishing costs as research and development expense rather than capitalizing these costs as inventory given a) the ongoing uncertainty associated with the conditional marketing authorization from the EMA and b) the fact that these product manufacturing and finishing costs were immaterial to its financial statements given that these costs amounted to less than [**]% of the Company's total aggregate operating expense for the same periods.

Prior to the receipt of conditional marketing authorization, a total of approximately $[**] of Translarna product manufacturing costs, which has since been directed for commercial supply, had been expensed as research and development costs.

PTC Therapeutics, Inc. respectfully requests that the information contained in Request #1 above be treated as confidential information and that the Securities and Exchange Commission provide timely notice to Shane Kovacs, Executive Vice President, Chief Financial Officer and Head of Corporate Development, PTC Therapeutics, Inc., 100 Corporate Court, South Plainfield, NJ, 07080, telephone 908-222-7000, before it permits any disclosure of the bracketed information contained in Request #1.

The Company has not completed a full manufacturing cycle for its product since it received conditional marketing authorization and has continued to expense early stage product manufacturing costs given the substantial uncertainty and risk related to the Company's ability to maintain its authorization to market Translarna which could therefore render all future product manufacturing for clinical research use.

Since the time of receiving the conditional marketing authorization, there has been, and continues to be, substantial uncertainty and risk related to the Company's ability to maintain its authorization to market Translarna for the treatment of nmDMD in the EEA. It is important to note that a conditional marketing authorization is subject to annual review and renewal by the EMA following its reassessment of the risk-benefit balance of the marketing authorization. The Company's conditional marketing authorization was further conditioned on its submission of the final report, including additional efficacy and safety data, from the Company's Phase 3 clinical trial of Translarna in patients with nmDMD (ACT DMD), which report was submitted to the EMA in January 2016. The Company's submission of this report is subject to review and consideration by the European Commission, EMA and CHMP.

In October 2015, the Company announced results from ACT DMD, including that the trial did not meet the primary efficacy endpoint in the 6-minute walk test with the pre-specified level of statistical significance. While the Company believes that the totality of clinical data from ACT DMD and its prior Phase 2b trial support the clinical benefit of Translarna for the treatment of nmDMD, there is substantial risk that the EMA and regulators in other geographic territories will not agree with the Company's interpretation of the results of ACT DMD and the totality of clinical data from its trials.

If the Company fails to satisfy the applicable renewal requirements for its conditional marketing authorization, or if the EMA determines that the balance of risks and benefits of using Translarna for nmDMD changes materially, the European Commission could, at the EMA's recommendation, vary, suspend, withdraw or refuse to renew the conditional marketing authorization for Translarna or require additional clinical trials.

In addition, other than with respect to the conditional marketing authorization, the Company does not have historical experience with, and has not proven its ability to successfully develop product candidates or obtain regulatory approvals to sell Translarna or its other product candidates and there currently are no other drugs approved for nmDMD and the regulatory process is still unknown.

Given the substantial risk with respect to the Company's ability to continue to generate future revenue from sales of Translarna under the conditional marketing authorization or otherwise, the Company concluded that it would be inappropriate to capitalize inventory for the year ended December 31, 2014 and the nine months ended September 30, 2015. The Company will continue to assess the appropriateness of inventory capitalization based on the outcome of applicable regulatory approvals.

Rule 83 Confidential Treatment by PTC Therapeutics, Inc. Request #2

With respect to royalties and other miscellaneous selling costs, and in the same context as determined with respect to product manufacturing and finishing costs, the Company determined that these costs were immaterial to its financial statements and classified them as research and development expense. This again was a result of both the ongoing uncertainty associated with the conditional marketing authorization from the EMA and the fact that these commercial supply-related costs were immaterial to its financial statements. For the nine months ended September 30, 2015 and for the year ended December 31, 2014, royalties expensed totaled $[**] and [**]$[**], respectively. For the same periods, miscellaneous selling costs, which consist of distribution costs, totaled $[**] and [**]$[**], respectively. Although such costs do not meet the definition of research or development under ASC 730-10-20, the royalties and other miscellaneous selling costs amount to less than [**]% of the Company's overall operating expense for the same periods and the inclusion of these costs in research and development expense do not materially impact the Company's financial statements or the trends therein with respect to the Company's increasing research and development expense over the affected reporting periods. Commencing with our 2015 Form 10-K, the Company will classify miscellaneous selling costs in selling, general and administrative expense.

As of September 30, 2015, approximately [**] zero cost units of finished Translarna product labeled for commercial sale were on hand. Commencing with the 2015 Form 10-K, the Company intends to disclose additional information concerning its use of zero-cost inventory as presented below under the heading "*Inventories and Cost of Product Revenues*."

PTC Therapeutics, Inc. respectfully requests that the information contained in Request #2 above be treated as confidential information and that the Securities and Exchange Commission provide timely notice to Shane Kovacs, Executive Vice President, Chief Financial Officer and Head of Corporate Development, PTC Therapeutics, Inc., 100 Corporate Court, South Plainfield, NJ, 07080, telephone 908-222-7000, before it permits any disclosure of the bracketed information contained in Request #2.

The following Table 1 reports the number of zero cost units sold in the fiscal year ended December 31, 2014 and each of the fiscal quarters ended March 31, June 30, and September 30, 2015 as well as the associated product manufacturing and finishing costs described above that were either incurred and expensed prior to receiving conditional marketing authorization or incurred following the Company's receipt of conditional marketing authorization for product that was directed for commercial sale.

Rule 83 Confidential Treatment by PTC Therapeutics, Inc. Request #3

Table 1.

Implied Cost of Translarna Product Sold and Expensed as R&D vs. COGS
($ in thousands)

	2014	Q1 2015	Q2 2015	Q3 2015
Units Sold	[**]	[**]	[**]	[**]
Cost of Translarna product-including manufacturing & finishing costs	$ [**]	$ [**]	$ [**]	$ [**]
Royalties on Translarna sales	$ [**]	$ [**]	$ [**]	$ [**]
Total implied cost of Translarna product sales expensed as R&D vs. COGS	**$ [**]**	**$ [**]**	**$ [**]**	**$ [**]**

The following Table 2 reports the implied cost of goods sold (COGS), implied gross profit and implied gross margin for fiscal year 2014 and each quarter in 2015 through September 30, 2015. As indicated in Table 2, had the Company capitalized all product manufacturing and finishing costs for Translarna product that was subsequently directed for commercial use at the time it was manufactured, the Company's gross profit margin would have been greater than 90%, which we believe is consistent with the cost of producing small molecule therapeutics in the pharmaceutical industry.

Table 2.

Implied Translarna Gross Profit and Gross Margin by period
($ in thousands)

	2014	Q1 2015	Q2 2015	Q3 2015
Translarna Revenue	**$ 717**	**$ 5,069**	**$ 6,161**	**$ 9,772**
Implied Translarna COGS	$ [**]	$ [**]	$ [**]	$ [**]
Implied Translarna Gross Profit	**$ [**]**	**$ [**]**	**$ [**]**	**$ [**]**
Implied Translarna Gross Margin	**[**]%**	**[**]%**	**[**]%**	**[**]%**

PTC Therapeutics, Inc. respectfully requests that the information contained in Request #3 above be treated as confidential information and that the Securities and Exchange Commission provide timely notice to Shane Kovacs, Executive Vice President, Chief Financial Officer and Head of Corporate Development, PTC Therapeutics, Inc., 100 Corporate Court, South Plainfield, NJ, 07080, telephone 908-222-7000, before it permits any disclosure of the bracketed information contained in Request #3.

Commencing with its 2015 Form 10-K, the Company intends to include the following disclosure in its Management's Discussion and Analysis of Financial Condition and Results of Operations to help the reader better understand the accounting and the expected gross margin for Translarna.

Inventories and Cost of Product Revenues

In 2014, we were notified that the European Commission, or EC, granted marketing authorization for Translarna for the treatment of nmDMD in ambulatory patients

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aged five years and older. The conditional marketing authorization allows us to market Translarna for the treatment of nmDMD in the 31 member states of European Economic Area. Our launch in these countries is on a country by country basis. This marketing authorization is subject to annual review and renewal by the EMA following its reassessment of the risk-benefit balance of the authorization, which we refer to as the annual EMA reassessment. The authorization was further conditioned on our submission of the final report, including additional efficacy and safety data, from ACT DMD and our ability to implement measures, including pharmacovigilance plans that are detailed in the risk management plan for Translarna that was submitted to EMA. In January 2016 we submitted the final ACT DMD report to the EMA. In the third quarter of 2015, the EMA approved the annual renewal of the marketing authorization for Translarna for the treatment of nmDMD. We plan to seek to renew the marketing authorization on an annual basis until our obligations have been fulfilled and the approval is converted from a conditional approval into a full approval. If we fail to satisfy such requirements, or if it is determined that the balance of risks and benefits of using Translarna changes materially, the European Commission could, at the EMA's recommendation, vary, suspend, withdraw or refuse to renew the marketing authorization for Translarna or require additional clinical trials.

Rule 83 Confidential Treatment by PTC Therapeutics, Inc. Request #4

We do not have sufficient history or experience from which to accurately forecast product sales or demand generation, and there continues to be substantial risk that regulators could suspend or not renew our marketing authorization in the future. As such, as of the date of this filing, we have not capitalized inventory. Had we capitalized all of our Translarna product that is available for commercial sale on hand as of [September 30, 2015], the value would have been approximately $[**]. In addition, had we expensed the cost of Translarna as a cost of sales when sold, our gross profit margin would have been greater than [**]%, which we believe is consistent with the cost of producing small molecule therapeutics for orphan drug diseases in the pharmaceutical industry. We will continue to assess the appropriateness of inventory capitalization based on the outcome of applicable regulatory approvals.

PTC Therapeutics, Inc. respectfully requests that the information contained in Request #4 above be treated as confidential information and that the Securities and Exchange Commission provide timely notice to Shane Kovacs, Executive Vice President, Chief Financial Officer and Head of Corporate Development, PTC Therapeutics, Inc., 100 Corporate Court, South Plainfield, NJ, 07080, telephone 908-222-7000, before it permits any disclosure of the bracketed information contained in Request #4.

Form 10-Q for the Quarterly Period Ended September 30, 2015
Notes to Consolidated Financial Statements
Note 2: Summary of significant accounting policies
Revenue Recognition
Net Product Sales, page 11

3. Please tell us whether you grant the right of return to your Translarna customers. If so, please tell us the provisions of your return policy and demonstrate to us how you were able to make reasonable estimates of returns as required by ASC 605-15-25-1f in order to record revenue upon product shipment effective January 1, 2015. In this regard, you disclose on page 4 of your 2014 Form 10-K that Translarna is the first ever approved treatment for the underlying cause of nonsense mutation Duchenne muscular dystrophy and that you did not launch Translarna on a commercial basis until December 2014.

Response to Comment No. 3

In response to the Staff's comment, with the exception of quality issues associated with the product, Translarna can generally only be returned if agreed upon in writing by the Company and the product is not opened nor in receipt by the final user/patient. As nmDMD is an ultra-orphan indication with a small patient base, the Company typically receives product orders directly from physicians for a specific patient with the prescription generally being written for a one to three month period. The product is typically shipped either directly to the physician's office or hospital for pick-up or directly to the patient's home. The Company ships Translarna to territories where the product is commercially approved or reimbursed through an approved early access program. Product is only shipped when a specific patient is approved by the government and an individual prescription is written. The right of return is eliminated as a matter of course when the product is dispensed to patients. In those countries where the Company has contracted with local third-party distributors, such distributors are not carrying, and have not carried, a significant amount of inventory given the Company's sales process and the relatively high cost of drug product. Since the initial product sale of Translarna in the third quarter of 2014, the Company has had no requests for product returns, nor any quality issues. The Company has determined that returns are expected to be minimal given this specialty distribution model which is typically utilized in the ultra-orphan disease space and, as such, has determined that it has a basis from which to make reasonable estimate of returns in accordance with ASC 605-15-25-1f.

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In connection with the Staff's comment letter, the Company acknowledges that:

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

- 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.

Should you have any further questions, please contact me at (908) 912-9466. Thank you for your time and attention to this matter.

Very truly yours,

/s/ Shane Kovacs
Shane Kovacs
Chief Financial Officer

cc: Office of Freedom of Information and Privacy Act Operations
Securities and Exchange Commission
100 F Street N.E., Mail Stop 2736
Washington, D.C. 20549
