PTC Therapeutics, Inc.
100 Corporate Court
South Plainfield, NJ 07080
908.222.7000
www.ptcbio.com

February 12, 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 our February 5, 2016 phone conversation with the Staff (the "Staff") of the Securities and Exchange Commission (the "Commission") as a supplement to the letter filed by us on January 21, 2016 in response to written comments of the Staff of the Commission in the letter dated December 15, 2015 (the "Comment Letter") from the Staff 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 further comment is reproduced below and the Company's corresponding response follows accordingly.

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

1. **We acknowledge your response to prior comment 2. Please clarify for us why you do not capitalize any manufacturing and finishing costs for Translarna product intended for commercial sale under the conditional approval in Europe. Please address the following:**

   - **Tell us why the ongoing uncertainty associated with the conditional approval as indicated in the last paragraph of the third page of your response is relevant to your accounting, explaining how expensing inventory costs is consistent with the requirement to carry inventory at the lower of cost or market as required by ASC 330-10-35.**
   - **Tell us the amount of your product manufacturing costs incurred in the first nine months of 2015 and the period from conditional approval through the end of 2014 that relate to Translarna manufacturing for commercial supply. Ensure that this amount does not include the finishing costs you provide in the last paragraph of the third page of your response.**
   - **Explain why it is appropriate to record any manufacturing costs associated with product sold commercially as R&D expense regardless of materiality.**

Response to Comment No. 1

Translarna™ (ataluren or PTC124), which is our most advanced product candidate, has been in development in various forms since 1998. Based on its understood mechanism of action, Translarna may have benefit in the treatment of patients with any genetic disorder that arises as a result of a nonsense mutation. We are currently pursuing Translarna as a treatment for five indications, the most advanced of which is Translarna for the treatment of nonsense mutation Duchenne muscular dystrophy, or nmDMD. However, we are also pursuing clinical development of Translarna for cystic fibrosis, MPS I, aniridia and genetically defined epilepsy, and we intend to commence clinical trials in additional indications over the next several years. As of January 16, 2016, Translarna has been manufactured and is being supplied for ongoing clinical studies in which approximately 700 patients or healthy volunteers are enrolled and for approximately 200 patients receiving Translarna on a commercial basis.

In 2010, we announced the results of our Phase 2b 48-week, 174-patient, double-blind, placebo-controlled clinical trial evaluating the efficacy and safety of Translarna in patients with nmDMD. We did not achieve the primary efficacy endpoint in the Phase 2b trial with the pre-specified level of statistical significance. In 2013, we initiated a Phase 3 48-week, 228-patient, double-blind, placebo-controlled, clinical trial to evaluate the efficacy and safety of Translarna in nmDMD patients. We refer to this Phase 3 trial as ACT DMD. In October 2015, we announced that we did not achieve the primary efficacy endpoint with the pre-specified level of statistical significance in the ACT DMD trial.

In 2011, we had submitted a new drug application, or NDA, to the U.S. Food and Drug Administration, or FDA, for approval of Translarna for the treatment of nmDMD, primarily based on our post-hoc analysis of the results of our Phase 2b trial. The FDA refused to file this

NDA on the grounds that the NDA did not contain substantial evidence of effectiveness based on the single placebo-controlled Phase 2b clinical trial which had not achieve statistical significance in the pre-specified analysis. At the time, the FDA provided us feedback regarding conducting a subsequent Phase 3 clinical trial which became our ACT DMD trial. In December 2015, we submitted a NDA to the FDA for approval of Translarna for the treatment of nmDMD, primarily based on our analysis of the results of our ACT DMD and Phase 2b trials. We anticipate that the FDA will notify us as to whether it has accepted our NDA filing in February 2016. If the NDA is accepted by the FDA, it is likely that the FDA will inform us of the date that their review of the NDA is expected to be completed. We anticipate, based on timelines established by the Prescription Drug User Fee Act, or PDUFA, that, if accepted, the FDA review date will be in late summer of this year. If the FDA determines that there is not substantial evidence of effectiveness from our ACT DMD and Phase 2b trials and that the benefit-risk profile of Translarna is not favorable, the agency could refuse to approve Translarna, issue a Complete Response letter to the company, and request the completion of additional clinical trials.

In 2012, also primarily based on the results of our Phase 2b trial, we submitted a marketing authorization application, or MAA, to the European Medicines Agency, or EMA, seeking conditional approval of Translarna for the treatment of nmDMD. Conditional approval from the EMA is a mechanism to provide for a marketing authorization subject to non-renewal if certain obligations are not met, typically related to providing comprehensive clinical data from ongoing studies that confirm the risk-benefit balance of a drug therapy is positive. In January 2014, EMA's Committee for Medicinal Products for Human Use, or CHMP, adopted a negative opinion recommending the refusal of the granting of the conditional marketing authorization for Translarna. Following our request for re-examination of the CHMP opinion, we were notified in August 2014 that the European Commission had approved a conditional marketing authorization for Translarna for the treatment of nmDMD under a limited label for ambulatory nmDMD patients aged five years and older who have been identified through genetic testing.

The marketing authorization received by the European Commission in August 2014 was further conditioned on our submission of the final clinical study report, including additional efficacy and safety data, from our ongoing ACT DMD trial, and our ability to implement several post-approval measures, including pharmacovigilance plans, that are detailed in our risk management plan with the European Commission. In addition, this marketing authorization is subject to an annual review and renewal by the EMA following its reassessment of the risk-benefit balance of the authorization. In January 2016, we submitted the results from our ACT DMD clinical trial to the EMA. In connection with our submission of the ACT DMD report to the EMA, we requested that this specific condition to our marketing authorization be removed. If the EMA does not view the results of ACT DMD as favorable, if we fail to satisfy our obligations under the marketing authorization, 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. We currently anticipate the CHMP will make its recommendation to the EMA with respect to this request in mid-2016.

We believe that the collective data from our Phase 2b and ACT DMD trials, including pre-specified analyses as well as retrospective and subgroup analyses that we have performed,

provide support for concluding that Translarna was efficacious and showed clinically meaningful improvements over placebo in these trials. However, we did not achieve the primary efficacy endpoint in either of our Phase 2b or ACT DMD trials with the pre-specified level of statistical significance and there is substantial risk that the FDA, the EMA and regulators in other territories will not agree with our interpretation of the results of ACT DMD and the totality of clinical data from our trials. This may result in the company not achieving full regulatory approvals to market and sell Translarna in the commercial setting in any jurisdiction. We expect to receive greater clarity on these regulatory outcomes within the next six months.

In the event that we are unable to obtain full regulatory approvals to market and sell Translarna in the commercial setting, we intend to direct substantially all work-in-process drug product to clinical supply. The same Translarna drug product can be manufactured and utilized across our numerous ongoing clinical trials as well as for commercial use.

Since our receipt of the conditional marketing authorization in the EEA, we have assessed on a quarterly basis whether to capitalize the manufacturing costs related to our commercial supplies of Translarna under ASC 330-10 and Statement of Financial Accounting Concepts No. 6, paragraph 25. Given the substantial uncertainty and risk related to our ability to maintain our marketing authorization for Translarna and the ongoing uncertainty of realizing future economic benefit with respect to commercial sales of Translarna, we have continued to expense manufacturing costs as research and development expenses.

Given the number of steps in our manufacturing process, a full manufacturing cycle can take between 18 months and two years to manufacture our drug product from start to finish. As Translarna can be utilized for either clinical or commercial, drug product is not directed to clinical or commercial use until the final finishing stage of the manufacturing process. Since receiving the conditional marketing authorization, we have not completed a full manufacturing cycle for Translarna and the majority of all work-in-process manufactured product may still be potentially directed toward clinical or commercial use. Sales of Translarna during 2014 and 2015 were fulfilled with Translarna product that had completed the manufacturing process with their associated product manufacturing costs being previously expensed as research and development costs in fiscal periods prior to receipt of the conditional marketing authorization. At the time that such manufacturing costs were expensed, all drug product manufactured was intended for clinical use.

Today, all work-in-process manufacturing product may still be ultimately utilized for clinical use and given the uncertainties associated with obtaining full regulatory approvals, we have decided to continue to expense these costs, which we believe is in line with industry practice when there is significant uncertainty with obtaining full approval from regulators. We will continue to assess, on a quarterly basis, the timing of inventory capitalization based on any

progress made with our regulatory processes over the coming months. However, we acknowledge the third bullet point of the Staff's comment and, commencing with our 2015 Form 10-K, we will record finishing costs associated with directing work-in-process drug product towards commercial drug packs as a sales, general and administrative expense. If we are able to obtain full regulatory approvals from either the EMA or the FDA such that we are able to assert probable future economic benefit, we plan to begin capitalizing manufacturing and finishing costs for work-in-

process, commercially-directed drug product as inventory. Concurrently, we will begin expensing these previously capitalized inventory costs as cost of goods sold as to better match expenses with revenues.

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

Total Translarna-related product manufacturing and finishing costs incurred in the first nine months of 2015 and for the year ended December 31, 2014, were approximately $[**] and $[**] million, respectively. Of these amounts, approximately $[**] million and $[**] million was directly incurred for clinical supply finishing costs and approximately $[**] million and $[**] million was directly incurred for commercial supply finishing costs. As noted above, we will classify these commercial finishing costs as sales, general and administrative expense, commencing with our 2015 Form 10-K. The remaining $[**] million and $[**] million, respectively, represent manufacturing costs for Translarna product that could be directed to either clinical or commercial use. We estimate that approximately [**]% of this work-in-process manufacturing production could ultimately be directed for commercial use in the future, which would imply that product manufacturing costs incurred during the first nine months of 2015 and the year ended December 31, 2014 for commercial supply was approximately $[**] million and $[**] million, respectively. Note however that should the company not receive full regulatory approvals from the FDA and EMA later this year, substantially all of this Translarna-manufactured product would be directed toward clinical supply, hence our rationale for recording these manufacturing costs as R&D expense given the uncertainty associated with obtaining regulatory approvals and the materiality of the amount relative to the company's overall operating expenses.

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.

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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