

UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

April 15, 2013

Via E-mail
Stuart M. Peltz, Ph.D.
Chief Executive Officer
PTC Therapeutics, Inc.
100 Corporate Court
South Plainfield, NJ 07080

Re: PTC Therapeutics, Inc.

Draft Registration Statement on Form S-1

Submitted March 18, 2013

CIK No. 0001070081

Dear Dr. Peltz:

We have reviewed your draft registration statement and have the following comments. In some of our comments, we may ask you to provide us with information so we may better understand your disclosure.

Please respond to this letter by providing the requested information and either submitting an amended draft registration statement or publicly filing your registration statement on EDGAR. If you do not believe our comments apply to your facts and circumstances or do not believe an amendment is appropriate, please tell us why in your response.

After reviewing the information you provide in response to these comments and your amended draft registration statement or filed registration statement, we may have additional comments.

General

- 1. Please submit all exhibits as soon as practicable. We may have further comments upon examination of these exhibits.
- 2. Please provide us proofs of all graphic, visual or photographic information you will provide in the printed prospectus prior to its use, for example in a preliminary prospectus. Please note that we may have comments regarding this material.
- 3. Please supplementally provide us with copies of all written communications, as defined in Rule 405 under the Securities Act, that you, or anyone authorized to do so on your behalf, present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not they retain copies of the communications. Similarly, please supplementally provide us with any research reports about you that are published or

distributed in reliance upon Section 2(a)(3) of the Securities Act of 1933 added by Section 105(a) of the Jumpstart Our Business Startups Act by any broker or dealer that is participating or will participate in your offering.

4. Comments to your application for confidential treatment will be delivered under separate cover.

<u>Prospectus Summary, page 1</u> Risks associated with our business, page 5

5. Please expand the second bullet point in this section to note that certain of your prior clinical trials were not successful in achieving specified primary endpoints.

Our corporation information, page 5

6. Please note that it is not appropriate to state or imply that you do not have liability for the statements in your registration statement. The statement "we have not independently verified" data obtained from third-party sources appears to imply that you are not taking liability for the statistical and other industry and market data included in your registration statement. In order to eliminate any inference that you are not liable for all of the information in your registration statement, please delete this statement or include a statement specifically accepting liability for these statements.

Risk Factors, page 11

7. Please include a risk factor discussing the risks associated with conducting a retrospective analysis after unblinding test results and explain why regulatory authorities typically give greatest weight to results from pre-specified analyses and adjusted p-values and less weight to results from post-hoc, retrospective analyses and nominal p-values.

"If clinical trials of our product candidates...," page 14

8. This extensive and lengthy risk factor highlights many material risks with more specific discussion than the heading may indicate. Please divide this risk factor into separate risk factors or provide subheadings highlighting more specifically each of the risks addressed. For example, you should include a separately headed risk factor or subheading discussing the possibility that the EMA will not grant conditional approval of ataluren for the treatment of DMD and that you may experience unforeseen events that could delay or prevent your ability to receive marketing approval or commercialize your product candidates.

Management's discussion and analysis of financial condition and results of operations, page 55 Critical accounting policies and significant judgments and estimates, page 59

9. Please disclose your election with respect to Section 107(b) of the JOBS Act and include a statement highlighting the risk that your financial statements may not be comparable to companies that comply with public company effective dates.

Share-based Compensation, page 60

- 10. Please provide the following information separately for each equity instrument issuance through the date of your response:
 - The date of the transaction,
 - The number of equity instruments granted or shares issued,
 - The exercise price of equity instruments granted if any,
 - Management's estimated fair market value per share and how the estimate was
 developed. Please disclose the judgments made regarding future trends and factors
 and indicate whether or not the valuation was contemporaneous or retrospective,
 - The identity of the recipient, indicating if the recipient was a related party,
 - The nature and terms of concurrent transactions; and,
 - The amount of any compensation or interest expense element.
- 11. After your IPO price range has been set, disclose each significant factor contributing to the difference between the fair value as of the date of each grant of equity instrument issued, including options, any warrants classified as equity instruments, and preferred stock and the estimated IPO price or when a contemporaneous valuation by an unrelated valuation specialist was obtained subsequent to the grants but prior to the IPO, the fair value as determined by that valuation. Reconcile and explain the differences between the mid-point of your estimated offering price range and the fair values included in your analysis. Please ensure that all of your equity instruments issued during the periods presented are included in your tabular disclosure. Revise your tabular disclosure as necessary to include information for all equity instruments issued subsequent to the balance sheet date through the date of your latest response.

Liquidity and Capital Resources, page 65

12. Please include a summary of all of the equity financing activities completed in the periods presented and through the date of your response. Please also clarify and discuss the "additional financing event" that is referred to in your Subsequent events note on page F-25.

Business, page 69

Our product development programs, page 72

13. Please expand your disclosure to indicate whether you have an IND for ataluren in each indication. Please also add disclosure regarding orphan designations.

Planned Phase 3 clinical trial of ataluren for nmDMD, page 76

14. Please describe how you intend to attract or recruit patients for your trials.

Regulatory status and strategy for nmDMD, page 79

15. Please expand your disclosure to discuss the extent to which you and potential investors may rely on the statement that "the FDA indicated that ... the study design for the proposed clinical trial, in general, was appropriate for providing evidence of efficacy of ataluren."

Post-hoc analysis of Phase 2b clinical trial data, page 84

16. Please explain on page 86 why regulatory authorities typically give greatest weight to results from pre-specified analyses and adjusted p-values and less weight to results from post-hoc, retrospective analyses and nominal p-values.

Safety and tolerability, page 91

17. Please specifically describe the adverse events observed during the trial, with particular focus on the serious adverse events. In addition, please explain how you determined that these serious adverse events were not ataluren-related.

Completed Phase 3 clinical trial of ataluren for nmCF, page 96

- 18. Please disclose why 34 patients withdrew prematurely from the trial.
- 19. You disclose on page 96 that the EMA has advised you of certain matters that may need to be further addressed in your MAA. Please briefly elaborate on the items provided in the bulleted list on page 96 to give added context to each of the matters to clarify the nature of the FDA's concerns and how you plan to address these in your MAA.

Safety and tolerability, page 99

20. Please specifically describe the adverse events observed during the trial, with particular focus on the serious adverse events. In addition, please explain how you determined that the most serious adverse events were "unrelated to study drug treatment."

Open label extension trial of ataluren for treatment of nmCF, page 100

21. Your disclosure indicates that you have not observed increases in frequency of previously reported adverse events or significant numbers of new adverse events in the open label extension trial. Please expand your discussion to disclose the adverse events you have observed noting the new adverse events particularly.

Intellectual Property, page 113

22. Your disclosure in the third paragraph of this section discusses the patent rights relating to ataluren owned by you. Please add similar disclosure regarding any material patent rights relating to ataluren that you license.

Competition, page 115

23. Please explain why you do not believe Kalydeco or the two other product candidates that Vertex is developing for the treatment of cystic fibrosis are applicable for the treatment of patients with nmCF.

Director compensation, page 142

24. We note your disclosure on page 143 that you intend to approve a compensation policy for non-employee directors that will become effective upon closing of the offering. Once approved, please update your disclosure to describe the adopted compensation plan.

Lock-up agreements, page 159

25. Once available, please file copies of each of the lock-up agreements.

Financial Statements

Statements of Operations, page F-4

26. Please tell us why you excluded the gain on exchange of convertible preferred stock in connection with your recapitalization and the beneficial conversion charge from your Net Loss for 2012.

Notes to Financial Statements Revenue Recognition, page F-10

27. Please tell us how the accounting policy that you recognize grant and collaboration revenue when invoiced is appropriate. Please also clarify whether there are any refund or repayment obligations associated with your grants. If so, please disclose the nature of these obligations and tell us how the recognition of revenue is appropriate. Please also tell us why you have classified the grant received as revenue as opposed to other income.

Beneficial conversion, page F-11

28. You disclose that the beneficial conversion feature results from the excess of the proceeds allocated to the Series Three convertible preferred stock. Please provide us with the computation of the beneficial conversion charge in 2012.

Fair value of financial instruments and investments, page F-13

29. Please disclose the assumptions used to determine the fair value of the warrant liability in 2012 and 2011.

Recapitalization, page F-17

- 30. Please disclose how you determined the value of the Series One, Series Two and Series Three preferred stock issued in connection with the July 2012 recapitalization. Please be sure to describe the model used to estimate the fair values and all of the relevant assumptions. Please also provide us with the computations of how you determined the fair value of the Series One, Series two and Series Three preferred stock.
- 31. Please tell us the business purpose of the recapitalization transaction completed in July 2012 from the perspective of the Series A though G holders of convertible preferred stock and the Series One, Series Two and Series Three convertible preferred stockholders and why the recapitalization made economic sense for each series of preferred stockholders. Please also tell us why only the Series One preferred stockholders contributed proceeds of \$29.7 million in the recapitalization transaction and why the Series A through G holders of preferred stock exchanged all of their interest for Series Two and Series Three preferred stock.
- 32. Please provide us with an analysis that supports your accounting for the gain of \$160 million in 2012 on the exchange of convertible preferred stock.

10. Collaborations and Grants Terminated Collaborations Genzyme, page F-21

- 33. Please disclose the amount of the additional payment received in exchange for an option to commercialize ataluren in indications other than nonsense mutation Duchenne muscular dystrophy outside the United States and Canada. Please also disclose how you accounted for deferred revenue when you received notification that Genzyme terminated the collaboration agreement.
- 34. You disclose that you recorded a one-time adjustment to your deferred revenue balance upon the restructuring of your agreement with Genzyme in August 2011 "to reflect the

value of the remaining performance obligations under the restructured agreement as represented by the best estimate of selling price." Please tell us how you calculated the adjustment to your deferred revenue in connection with this restructuring and all of the relevant assumptions.

35. While you disclose on page F-10 that you use the "updated multiple element revenue recognition guidance" for material modifications to your collaborations, it is unclear how you determined that there was a material modification. Please revise your disclosures to clarify how you determined that the modifications were material.

Roche and SMA Foundation, page F-22

36. Please disclose the estimated performance period and the factors considered in determining what appears to be a relatively short performance period.

14. Subsequent events, page F-25

- 37. You disclose that in March 7, 2013 you issued and sold 4,497,035 shares of series four senior preferred stock and an aggregate of 502,919 shares of your series four senior preferred stock upon conversion of the convertible promissory notes issued in January and February 2013. Please disclose how you plan to account for the January and February 2013 convertible promissory note issuances, for the conversion of the convertible promissory notes, for the issuance of warrants at an exercise price of \$.01 and for the exchange of the outstanding preferred stock that resulted in another recapitalization event.
- 38. Please disclose how you determined the value of the Series One, Series Two and Series Three preferred stock issued in connection with the March 7, 2013 recapitalization. Please be sure to describe the model used to estimate the fair values and all of the relevant assumptions. Please also provide us with the computations of how you determined the fair value of the Series One, Series two and Series Three preferred stock.

General

If you intend to respond to these comments with an amended draft registration statement, please submit it and any associated correspondence in accordance with the guidance we provide in the Division's October 11, 2012 announcement on the SEC website at http://www.sec.gov/divisions/corpfin/cfannouncements/drsfilingprocedures101512.htm.

Please keep in mind that we may publicly post filing review correspondence in accordance with our December 1, 2011 policy (http://www.sec.gov/divisions/corpfin/cfannouncements/edgarcorrespondence.htm). If you intend to use Rule 83 (17 CFR 200.83) to request confidential treatment of information in the correspondence you submit on EDGAR, please properly mark that information in each of your

confidential submissions to us so we do not repeat or refer to that information in our comment letters to you.

You may contact Ibolya Ignat, Staff Accountant, at (202) 551-3656 or Gus Rodriguez, Accounting Branch Chief, at (202) 551-3752 if you have questions regarding comments on the financial statements and related matters. Please contact Karen Ubell, Staff Attorney, at (202) 551-3873, Dan Greenspan, Legal Branch Chief, at (202) 551-3623 or me at (202) 551-3715 with any other questions.

Sincerely,

/s/ Daniel Greenspan for

Jeffrey P. Riedler Assistant Director

cc: Via E-mail

Clark W. Petschek

Wilmer Cutler Pickering Hale and Dorr LLP