

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

May 30, 2013

Via E-mail
Ramesh Kumar, Ph.D.
President and Chief Executive Officer
Onconova Therapeutics, Inc.
375 Pheasant Run
Newtown, PA 18940

Re: Onconova Therapeutics, Inc.

Confidential Draft Registration Statement on Form S-1

Submitted May 3, 2013 CIK No. 0001130598

Dear Dr. Kumar:

We have reviewed your confidential 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 confidential 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 confidential draft registration statement or filed registration statement, we may have additional comments.

General

- 1. Please submit all outstanding 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. We will deliver comments to your confidential treatment request under separate cover.
- 5. Please update your filing to include unaudited interim financial statements and related financial schedules for the quarterly periods ended March 31, 2013 and 2012 as required by Rule 3-12 of Regulation S-X.
- 6. Please provide the information required (including Exhibit 16) under Regulation S-K Item 304 and Item 11(i) of Form S-1 regarding the change in accountants for year 2012.

Risk Factors

"Our product candidates may cause undesirable side effects...," page 16

7. Please expand the discussion in this risk factor to disclose the extent to which you have observed undesirable side effects in your trials, including any safety or toxicity issues, and the impact, if any, on the prospects for obtaining marketing approval of your product candidates. We note, for example, your disclosure on pages 85-88 detailing certain drug-related adverse events occurring in your rigosertib trials.

Special Note Regarding Forward-Looking Statements and Industry Data, page 46

8. Please note that it is not appropriate to state or imply that you do not have liability for the statements in your registration statement. Your statements at the bottom of page 47 that you have not independently verified market and industry data obtained from third-party sources or your own internal company research could 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 these statements or include a statement specifically accepting liability for these statements.

Use of Proceeds, page 48

9. We note your statement that you have not yet determined the amount of proceeds to be spent on any of the areas listed in the second paragraph of this section, such as research and development and clinical trial expenditures. However, if the company has specific purposes in mind for the use of proceeds, Item 504 of Regulation S-K requires disclosure

of the approximate amount intended to be used for each such purpose. This is required even if, as you note in your prospectus, management will have broad discretion in allocating the proceeds and that the ultimate use of proceeds will depend on several contingencies and is subject to change.

Management's Discussion and Analysis of Financial Condition and Results of Operations Financial Overview, page 57

10. We note your disclosure of "research funding" for 2011 and 2012 in the table on page 57. Please clarify the amount of research funding attributable to payments from LLS.

Research and Development Expenses, page 62

- 11. You state on page 59 that research and development activities are central to your business model and that you plan to increase your research and development expenses for the foreseeable future. While you state that you do not currently utilize a formal time allocation system to capture expenses on a project-by-project basis, please expand your disclosure to provide the following:
 - The costs you do track by project for each period presented and to date and a reconciliation of the total of these project costs to the total expenses presented on your statement of operations and comprehensive loss. In this regard, it appears, for example, that you may track external cost by project as you are able to quantify on page 70 that \$8.4 million of the increase in research and development expenses in 2012 as compared to 2011 relates to clinical trials expenses for rigosertib.
 - Explain why management does not maintain and evaluate all research and development costs by project. Explain how you use functional area expenditures to evaluate and prioritize your R&D activities.
 - Explain how you monitor development progress for individual projects.
 - Absent costs by project, please provide other quantitative or qualitative disclosure that indicates the amount of the company's resources being used on the project such as by stage of development (i.e. discovery, pre-clinical, clinical phase I, clinical II and phase III) and/or other meaningful breakout.

Stock-Based Compensation, page 63

- 12. We have the following comments regarding your disclosure and accounting for stock-based compensation:
 - Since you have not disclosed an estimated offering price we are deferring a final evaluation of stock compensation and other costs recognized until the estimated offering price is specified. We may have further comments in this regard when the amendment containing that information is filed.

- In the first paragraph of your discussion about the fair value of stock option grants from January 1, 2011 to February 1, 2012 you indicate that you utilized an assumed annual volatility rate of 64.0% based on historical share price trading data for a group of 10 companies you considered comparable to yours. Please tell us the name of these 10 companies and explain to us why you deemed them to be comparable to you. In your response, for each of these companies tell us the following information at your valuation date:
 - o annual revenues;
 - o annual product revenues;
 - o net income/loss;
 - o assets;
 - o equity;
 - o number of products in development and their stages of development; and
 - o number of marketed products
- Please provide in your filing containing the IPO price range, a discussion of each significant factor contributing to the difference between the fair value as of the date of each grant and the estimated IPO price range. Please reconcile and explain the differences between the mid-point of your estimated offering price range and the fair values included in your analysis.

Operating and Capital Expenditure Requirements, page 73

13. To the extent practicable, please quantify the estimated costs mentioned in this section that you will incur as a result of being a public company.

Business, page 81 Our Product Candidates, page 79

- 14. Please disclose in this section whether there is an effective investigational new drug application (IND) for each of the following:
 - Rigosertib for treatment of higher risk MDS in intravenous formulation
 - Rigosertib for treatment of lower risk MDS in oral formulation
 - Rigosertib for treatment of head and neck cancer
 - Rigosertib for treatment of pancreatic cancer
 - ON 013105 for treatment of lymphoma
 - Recilisib for treatment of ARS

In each case, if an IND has been filed for the compound and corresponding treatment indicated, please disclose the identity of the filer and the date of filing. If an IND has not been filed, please explain why.

Treating Myelodysplastic Syndromes, page 81

15. Please explain how the mechanism of action for hypomethylating drugs differs from rigosertib. Specifically, please clarify why rigosertib does not pose the same risk of patient failure and drug resistance as azacitidine or decitabine, the current standard of care for higher risk MDS patients.

Phase 1/2 Trial Results of Rigosertib in Patients with Myelodysplastic Syndromes, page 83

16. Please clarify the reason why a follow-up bone marrow biopsy was only available for 30 of the 39 patients treated in these clinical trials. Please also disclose whether you expect any similar difficulties in obtaining follow-up biopsies in the ONTIME trial. If so, explain what effect, if any, this could have on the evaluation of trial results and the support of efficacy claims for rigosertib.

Collaborations, page 90

17. Please clarify in this section whether your \$10.2 million in government funding for recilisib was part of a formal agreement with the Department of Defense. If so, please describe the material terms of that agreement and the parties' respective obligations in this section and file the agreement as an exhibit to the registration statement.

The Leukemia and Lymphoma Society

18. Please explain more specifically what "advancing the clinical development of rigosertib" means under the terms of the LLS agreement, as well as the process for determining that the company has failed to fulfill this obligation.

Intellectual Property, page 93

- 19. We note your research agreement with Mount Sinai School of Medicine. Please disclose all material terms of that agreement in this section, including which, if any, of your products and patents are implicated under this research agreement. Please also file this agreement as an exhibit to the registration statement.
- 20. Please disclose whether you license or own the composition-of-matter patent and the method of treatment patent for rigosertib.

Manufacturing, page 96

21. Please identify the material terms of your manufacturing and supply agreements. Please file these agreements as exhibits to the registration statement as well. Alternatively, if you do not believe any of these agreements is material, please advise us as to the basis of your conclusions.

Management, pages 113-115

22. We note your discussion of consulting agreements with certain members of your clinical advisory and scientific advisory boards "covering their respective financial arrangements." Please describe payments and other material terms of these agreements and file them as exhibits to the registration statement. If you do not believe these agreements are material, please advise us as to the basis of your conclusions.

Shares Eligible for Future Sale, page 144

23. Once available, please file the form of lock-up agreement as an exhibit to your registration statement.

Consolidated Financial Statements
Notes to Consolidated Financial Statements
Report of Independent Registered Public Accounting Firm, page F-3

24. Please tell us if May 2, 2013 is the original signature date for EisnerAmper LLP's audit of your financial statements for the year ended December 31, 2011. If not, tell us the original signature date and the reason(s) it changed. Tell us if any of the adjustments referred to on pages 68-69 related to and were recorded in year 2011 as a restatement of those financial statements.

15. License and Collaboration Agreements Baxter Agreement, page F-34

- 25. In 2012, you recognized \$42.4 million in revenue relating to the Baxter agreement. Please address the following and reference for us any authoritative literature you relied upon to support your position:
 - Please elaborate on your assertion that the license has standalone value to Baxter. In your response, tell us how Baxter can exploit the license without the additional development services that you are obligated to perform. Tell us:
 - whether and how Baxter or any other party can perform these development services given your expertise with your intellectual property;
 - whether Baxter has the rights and full access to past and future intellectual information in order to obtain regulatory approval of rigosertib in Europe;
 - whether Baxter is performing any development activities related to rigosertib; and
 - how the fact that you will own all marketing approvals and regulatory filings pursuant to section 6.1 of your agreement with Baxter filed as Exhibit 10.1 to your draft submission impacts Baxter's ability to exploit the license.

- Please tell us why it is appropriate to recognize the revenue allocated to the
 research and development services deliverable through March 31, 2014 when it
 appears that you are obligated to file all regulatory submissions in Europe and it
 appears unlikely that you will be in a position to have these submissions filed and
 approved by then.
- Please tell us why you do not believe your participation on the joint committee as disclosed in the third paragraph on page F-36 is a deliverable under your Baxter agreement. In your response, please tell us:
 - o the composition of the committee;
 - o the term of the committee;
 - o your obligation to participate;
 - o what happens if you do not participate; and
 - o the dispute resolution provisions.
- 26. Please revise your filing to disclose each individual potential future milestone you could receive and its related contingent consideration as required by ASC 605-28-50-2b.

Index to Exhibits, page II-7

27. Please file your joint venture agreement with GVK Biosciences as an exhibit to your registration statement.

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 Jim Peklenk at (202) 551-3661 or Mark Brunhofer at (202) 551-3638 if you have questions regarding comments on the financial statements and related matters. Please contact Austin Stephenson at (202) 551-3192, Dan Greenspan 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: <u>Via E-mail</u>

David S. Rosenthal, Esq.

Dechert LLP