



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

DIVISION OF
CORPORATION FINANCE

Mail Stop 4720

December 11, 2015

Pankaj Mohan, Ph.D.
President and Chief Executive Officer
Oncobiologics, Inc.
7 Clarke Drive
Cranbury, New Jersey 08512

**Re: Oncobiologics, Inc.
Draft Registration Statement on Form S-1
Submitted November 16, 2015
CIK No. 0001649989**

Dear Dr. Mohan:

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.

Overview, page 1

1. Please clarify the meaning of any significant scientific or technical terms the first time they are used in your prospectus in order to ensure that lay readers will understand the disclosure. For example, please define each of the following at their first use:
 - mAbs;
 - pharmacokinetic, or PK; and
 - PK bioequivalency criteria.
2. Your product pipeline table should highlight your product candidates in development that are reasonably likely to result in an approved product in the foreseeable future. Research and discovery activities that precede the identification of a product candidate are too

remote to be highlighted in the pipeline table. Accordingly, please limit your table to product candidates where you have selected a clone for development.

3. Please include disclosure in your prospectus summary to state the approved therapeutic use for the referenced product and for which indications you initially intend to seek approval for your product candidates. In addition, please disclose how the product is intended to be delivered (e.g. pill formulation or injection).

Risk Associated with Our Business, page 3

4. Please supplement your list of bullet point risk factors to address the following:
 - that, to your knowledge, there has been only one biosimilar product application approved by the FDA under the 351(k) pathway to date;
 - your reliance and the other material risks relating to your collaboration and licensing agreements; and
 - that you have no issued patents, and the risks associated with any failure to obtain and maintain protection of your own intellectual property.

The results of previous clinical trials may not be predictive of future results..., page 18

5. Please revise this risk factor to identify the indications for which you initially intend to seek approval. If you intend to extrapolate clinical data intended to support a demonstration of biosimilarity in one indication to support approval of your biosimilar candidate in one or more additional indications, please so state, and describe the risks related to such extrapolation.

We currently engage single source suppliers for clinical trial services, page 30

6. We note this risk factor discusses the risks associated with your multiple source suppliers for fill-finish manufacturing and does not discuss the single source suppliers for clinical trials. In that regard, we refer to your last risk factor on page 28. Please revise your disclosure in this or a separate risk factor to discuss the risks relating to your sole supplier for “specialty-manufactured bags.” In addition, please disclose whether you believe alternate sources of the specialty-manufactured bags are available.

If we infringe or are alleged to infringe intellectual property rights..., page 30

7. Please revise your disclosure to describe briefly the “freedom to operate analyses” in layman’s terms.

We may be subject to claims that our employees..., page 33

8. Please revise your disclosure to state that Genentech, former employer of Dr. Mohan and Dr. Bahrt, developed bevacizumab (Avastin), for which you seek to develop ONS-1045

as a biosimilar, and trastuzumab (Herceptin), for which you seek to develop ONS-1050 as a biosimilar. In addition, please identify any similar circumstances that increase the risk of the claims described in this risk factor.

Use of Proceeds, page 52

9. Please revise your Use of Proceeds to state whether each of the allocated proceeds will allow you to fund your clinical products and the expansion of your facility to completion. If not, please describe how far in the trial process you anticipate the allocated proceeds will allow you to reach for each of your product candidates and the extent of your facility expansion.
10. Please revise your Use of Proceeds table to separate the amounts to be used to fund research and development activities from the amounts to be used for working capital and general corporate purposes.

Collaboration and License Agreements

Huahai — Humira (ONS-3010) and Avastin (ONS-1045), page 61

11. Please clarify whether the strategic license agreement with Huahai is the same as the co-development and license agreement described here and on page 86. We may have additional comments.

Collaboration Revenues, page 63

12. Please revise to quantify, in a tabular format, the components (i.e. upfront fees, milestones, deferred revenues, etc.) of your collaboration revenues for each period presented.

Research and Development Expenses, page 64

13. For each of your key research and development projects, please revise to disclose research and development costs incurred during each period presented and inception to date. For the remainder of projects not considered individually significant, disclose the composition of the total R&D expense for each period presented. If you do not track these costs by project please revise your disclosure to clarify.

Stock-Based Compensation and PSU Obligation, page 68

14. We may have additional comments on your accounting for equity issuances including stock compensation and beneficial conversion features. Once you have an estimated offering price, please provide us an analysis explaining the reasons for the differences between recent valuations of your common stock leading up to the IPO and the estimated offering price.

ONS-3010 – Adalimumab (Humira) Biosimilar, page 77

15. Please revise your disclosure to explain what “luminescence” is and how it demonstrates potency.
16. Please revise the table of most frequently reported adverse events on page 79 to clarify what you mean by “Preferred Term.”

Our Product Candidate Portfolio, page 77

17. Please revise your disclosures for each of your clinical trials to state the jurisdiction and the governing body pursuant to which the clinical trials were performed and where you intend to perform your Phase 3 trials. For example, if a clinical trial was conducted in the United States pursuant to an IND issued from the FDA, please so state and include the date of the IND. In addition, include conforming disclosure in your prospectus summary.

Chemistry Manufacturing Controls, or CMC, Status, page 78

18. We note your disclosure that a novel formulation of similar stability was developed and utilized in the Phase 1 clinical trial. Please revise your disclosure, if applicable, to discuss whether you will be utilizing the same formulation in your Phase 3 trials and, if not, describe whether you believe any such change will affect your Phase 3 trials.

Selexis — Humira (ONS-3010), Avastin (ONS-1045) and Herceptin (ONS-1050), page 82

19. We refer to your research license agreement, as amended. Please revise your prospectus to describe the material terms of this agreement, including:
 - the initial fee;
 - milestone payments; and
 - aggregate amounts paid to date.

Commercial License Agreements, page 83

20. We refer to your disclosure of your commercial licensing agreements. For each of the agreements, please revise your prospectus to describe the material terms, including:
 - up-front or execution payments;
 - milestone payments;
 - royalty termination fees; and
 - aggregate amounts paid to date.

In addition, please file these agreements as exhibits in accordance with Item 601 of Regulation S-K.

IPCA — Humira (ONS-3010), Avastin (ONS-1045) and Herceptin (ONS-1050), page 83

21. We refer to each of your license agreements described on pages 83 and 84. Please revise your prospectus to describe the material terms of each of the agreements, including:
- up-front or execution payments;
 - milestone payments;
 - royalty rates within 10% (e.g. low teens, twenties, etc.);
 - development payments;
 - commercialization fees; and
 - aggregate amounts received to date.

In addition, please file the agreements as exhibits in accordance with Item 601 of Regulation S-K.

Liomont — Humira (ONS-3010) and Avastin (ONS-1045), page 84

22. Please revise your prospectus to describe the material terms of your agreement, including:
- the up-front or execution payment;
 - milestone payments; and
 - royalty rates within 10% (e.g. low teens, twenties, etc.).

In addition, please file the agreement as an exhibit in accordance with Item 601 of Regulation S-K.

Huahai — Humira (ONS-3010) and Avastin (ONS-1045)
Co-Development and License Agreement...page 86

23. Please revise your prospectus to describe the material terms of the license agreement, including:
- the up-front or execution payment; and
 - milestone payments.

In addition, please file the agreement as an exhibit in accordance with Item 601 of Regulation S-K.

Intellectual Property, page 87

24. Please revise your disclose to identify the applicable jurisdictions and the anticipated patent expiration dates for each of your patent applications.
25. We refer to your “Collaboration and License Agreements” on page 82. We note that you are currently licensing rights to the Selexis Technology pursuant to your agreements with

Selexis. Please revise your disclosure in this section to describe any material patents and patent applications that you license, including:

- nature of the patent and the type of patent protection such as composition of matter, use or process; and
- patent expiration dates or expected expiration dates for patent applications by jurisdiction.

Compensation Committee Interlocks and Insider Participation, page 99

26. We refer to your disclosure that none of your executive officers currently serves, or has served during the last year, as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving as a member of our board of directors or compensation committee. We refer to each of the biographical disclosures for Dr. Mohan and Mr. Griffith and their respective positions with Sonnet Biotherapeutics, Inc. Please tell us why you believe Dr. Mohan and Mr. Griffith do not meet the disclosure requirements of this section. In the alternative, please revise this section to provide the relevant disclosures for Dr. Mohan and Mr. Griffith

Agreement with Named Executive Officers, page 103

27. Please revise your disclosure for each of your named executive officers to disclose whether each agreement is for full or part-time services, whether the named executive officer is currently performing their duties on a full or part time basis, term and termination provisions.

Loans and Guarantees, page 116

28. Please revise your description of the amounts owed to Dr. Mohan to disclose any interest accruing on such amounts.

Other Comments

29. Please submit all exhibits as soon as practicable. We may have further comments upon examination of these exhibits.
30. Please confirm that the graphics included in your registration statement are the only graphics you will use in your prospectus. If those are not the only graphics, please provide any additional graphics prior to their use for our review.
31. 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.

Pankaj Mohan, Ph.D.
Oncobiologics, Inc.
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You may contact James Peklenk at (202) 551-3661 or Sharon Blume at (202) 551-4407 if you have questions regarding comments on the financial statements and related matters. Please contact Tara Keating Brooks at (202) 551-8336, Amy Reischauer at (202) 551-3793, or me at (202) 551-3675 with any other questions.

Sincerely,

/s/ Suzanne Hayes

Suzanne Hayes
Assistant Director
Office of Healthcare and Insurance

cc: Via E-mail
Yvan-Claude Pierre
Cooley LLP