

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

DIVISION OF CORPORATION FINANCE

July 29, 2014

<u>Via E-mail</u> Yuval Cohen, Ph.D. Chief Executive Officer Corbus Pharmaceuticals Holdings, Inc. 100 River Ridge Road Norwood, MA 02062

# Re: Corbus Pharmaceuticals Holdings, Inc. Confidential Draft Registration Statement on Form S-1 Submitted July 2, 2014 CIK No. 0001595097

Dear Dr. Cohen:

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 file the March 27, 2014 merger agreement as an exhibit to your registration statement.
- 3. 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.
- 4. 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.

- 5. Please address the following with respect to the reverse acquisition:
  - Provide a complete analysis of your accounting treatment with references to the technical guidance upon which you relied. Clarify in the filing if you accounted for the reverse acquisition as a business combination or a recapitalization.
  - Since the private placement occurred simultaneously with the reverse merger, please address the appropriateness of JB Therapeutics being the accounting acquirer considering the total shares outstanding after the private placement.
  - If you accounted for the reverse acquisition as a business combination, please consider the need for pro forma information pursuant to Article 11 of Regulation S-X.
  - Please include the financial statements for Corbus Pharmaceuticals Holdings, Inc. for the period ended June 30, 2014, including a Statement of Shareholders' Equity. If the reverse acquisition is accounted for as a business combination, include the financial statements for the two years ended December 31, 2013.
  - Retroactively restate the shares outstanding in the historical financial statements of JB Therapeutics to reflect the shares issued in the reverse merger, revise the earnings per share, and any equity issuances taking into consideration the exchange ratio.

## Prospectus Summary Overview, page 1

6. We note your disclosure that your product candidates treat "orphan" diseases with clear unmet medical needs. "Orphan" has a specific meaning in FDA regulations, and your product candidates have not yet received orphan designation from the FDA. As such, you should revise disclosure here and throughout the prospectus as applicable to remove any possible inference that your product candidates have been granted orphan designation. You may retain disclosure indicating that you intend to seek such designation and an explanation of the process and benefits if granted.

## Our Pipeline, page 2

7. In footnote or narrative disclosure to the pipeline chart on this page, you should disclose the identity of the entity that conducted pre-clinical and Phase 1 safety trials for Resunab and when these trials were conducted. Please additionally disclose, if true, that you expect to rely on data from these completed Phase 1 studies in order to file your INDs and launch directly into Phase 2.

### **Risk Factors**

"Our cash or cash equivalent will only fund our operations for a limited time...," page 9

8. You should disclose in this section your total outstanding debt, of which \$169,000 is currently in default. Describe the risks, if any, pertaining to the effects that your current default could have on your ability to secure additional financing.

Management's Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Policies and Estimates Accounting for Stock-Based Compensation, page 37

- 9. We may have additional comments on your accounting for stock compensation once you have disclosed an estimated offering price. Please supplementally provide us with a quantitative and qualitative analysis explaining the difference between the estimated offering price and the fair value of <u>each</u> equity issuance <u>through the date of effectiveness</u> for the preceding twelve months.
- 10. Please revise your disclosure to state that the valuations are highly subjective and that you will no longer be required to estimate the fair value of your common shares underlying new equity awards once those shares begin trading.
- 11. Please revise the Stock Compensation section to discuss the equity issuances of the registrant. Please disclose the valuation methods used and the nature of material assumptions for valuations performed since inception.

### Business Overview, page 41

12. Please expand the discussion to include the general development of your business and any predecessor(s) during the past five years pursuant to Item 101(a) of Regulation S-K. In this regard, we note your disclosure eon page 9 that you have been engaged in developing Resunab since 2009. Please describe your reverse merger and the extent of JB Therapeutics, Inc.'s operations and business prior to the merger. The discussion should include any material research and development carried on by JB Therapeutics relating to Resunab prior to the merger.

### Effect of Resunab in Fibrotic Disease Animal Models, page 47

- 13. Please explain in greater detail how you were able to translate the effects observed in *in vivo* animal models to *ex vivo* human models as part of the Resunab mouse study, and disclose whether there are any risks or limitations inherent in such translation. Further, explain the significance of reduced TGF-beta levels to anti-fibrotic/anti-inflammatory activity.
- 14. We note your disclosure that the responses observed in the *ex vivo* model were statistically significant. Please disclose the specific results, how you measured statistical significance, and the related p-values.

### Human Clinical Results to Date, page 47

- 15. You disclose that the Phase 1 and Phase 2a clinical trials were conducted by "a prior licensee" developing Resunab. Please identify the licensee and discuss the current status of the prior development program, including the current status of any underlying agreement with the prior licensee.
- 16. In describing the first Phase 1 study, you disclose that there were only 3 patients reporting "treatment related" adverse events, but later disclose that "the relevance to the drug was considered unlikely." Please reconcile these two characterizations in your disclosure. Please additionally disclose the type of adverse events experienced by these 3 patients.
- 17. We note your disclosure that the adverse events observed in the second Phase 1 study were not "clinically significant." Please explain what you mean by clinically significant in this context. Please additionally disclose how many patients experienced adverse events and whether any were considered treatment-related.
- 18. Regarding the completed Phase 2a trial, please disclose, if true, that you may not rely on the efficacy results discussed here to support your current clinical program, as the Phase 2a trial was designed to measure reduction in pain while your future studies will have completely different efficacy endpoints.

<u>Clinical Development Plan</u> <u>Overview, page 48</u>

19. In the first paragraph on this page, please briefly describe the requirements for fast-track designation. Please additionally disclose the other, specific pathway(s) for "accelerated approval" referred to in this section.

#### Intellectual Property, page 49

- 20. We note your disclosure that you have submitted 3 new patent applications for Resunab. You should additionally disclose information regarding your material issued patents, if any, granted under the assignment of the intellectual property from Dr. Burstein. In describing any such issued patents, you should discuss the nature of the property covered, the protection afforded, jurisdiction, and date of expiration. If you do not currently hold any material issued patents, you should so disclose.
- 21. Please describe the material terms of any underlying assignment agreement that you have with Dr. Burstein, and file it as an exhibit to your registration statement pursuant to Item 601(b)(10) of Regulation S-K.

#### Management, page 58

- 22. Please disclose Dr. Tepper's principal occupations and employment during the past five years and the name and principal business of any corporation or other organization in which such occupations and employment were carried on in accordance with Item 401(e)(1) of Regulation S-K.
- 23. Please explain how Dr. Zurier joined Corbus Pharmaceuticals in 2009. For example, if you refer to a predecessor company to Holdings prior to the 2014 reverse merger (i.e., JB Therapeutics, Inc.), you should clarify your disclosure. Please make a similar clarification where you reference Corbus Pharmaceuticals in Mr. Moran's biography.

### Principal Stockholders, page 69

24. It appears that there are several selling stockholders included in the table on page 78 that beneficially own greater than 5% of your outstanding shares of common stock but that do not appear in the principal stockholders table on this page. Please reconcile this discrepancy in your disclosure or explain to us the basis for the exclusion of such stockholders from the principal stockholders table.

### Selling Stockholders, pages 77-81

25. You disclose that the selling stockholders listed in the table have sole voting and investment power with respect to all shares of common stock beneficially owned by them unless otherwise indicated. Many of the selling stockholders in the table are entities rather than natural persons. For all selling stockholders that are not natural persons, please identify the person or persons who have voting or investment control over the company's securities that the entity owns in footnotes to the table. We refer you to Questions 140.02 of the Regulation S-K Compliance & Disclosure Interpretations.

- 26. Please note that registration statements registering the resale of shares offered by brokerdealers must identify the broker dealers as underwriters if the shares were not issued as underwriting compensation. Additionally, for those selling stockholders that are affiliates of broker-dealers, please advise us as to whether:
  - each seller purchased the securities in the ordinary course of business; and
  - at the time of purchase of the securities to be resold, the seller had any agreements or understandings, directly or indirectly, with any person to distribute the securities.

Please additionally include this disclosure in the prospectus.

## Notes to Unaudited Condensed Financial Statements 11. Subsequent Event, page F-12

27. You state in "Merger Agreement" on page 4 that in connection with the Merger, holders of outstanding options of JB Therapeutics received, in substitution for such options, options to purchase an aggregate of 905,334 shares of your common stock with exercise prices ranging from \$0.11 to \$0.17 per share. Please update the subsequent event footnotes on pages F-12 and F-30. In addition, it does not appear that Item 15 on page II-3 has properly reflected all option issuances. Please revise as appropriate.

<u>Notes to Financial Statements</u> <u>3. Significant Accounting Policies</u> Research and development expenses, page F-19

28. Please explain your basis for netting revenue under the SIBR research grant against research and development expenses, as disclosed on page 39. Refer us to the authoritative literature upon which you relied.

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 Frank Wyman at (202) 551-3660 or Mary Mast at (202) 551-3613 if you have questions regarding comments on the financial statements and related matters. Please contact Austin Stephenson at (202) 551-3192, John Krug at (202) 551-3862, 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> Steven M. Skolnick, Esq. Lowenstein Sandler LLP