

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

DIVISION OF CORPORATION FINANCE

October 14, 2014

<u>Via E-mail</u> David M. Renzi Carbylan Therapeutics, Inc. 3181 Porter Drive Palo Alto, CA 94304

Re: Carbylan Therapeutics, Inc. Draft Registration Statement on Form S-1 Submitted September 19, 2014 CIK No. 0001348911

Dear Mr. Renzi:

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 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.
- 2. We note that you have submitted an application for confidential treatment relating to one of your exhibits. Please be advised that we will review this application separately and comments issued as a result of that review, if any, must be resolved prior to your filing a request for acceleration.

<u>Summary</u> <u>Overview, page 1</u>

- 3. Please clarify in this section that the term "intra-articular" refers to something occurring within or administered by entry into a joint.
- 4. Please explain here and wherever else applicable in your submission your statement that your Phase 2b study, COR1.0, was "not powered for statistical significance."

Hydros-TA Clinical Program, page 3

- 5. Consistent with your response to our immediately preceding comment, please note here, and in the risk factor on page 13-14, that the only statistically significant result detected in the COR1.0 study was a comparison between Hydros-TA and Hydros at the 2-week mark, and no other time point, and not at all between either of them and Synvisc-One.
- 6. Please note here that you intend to seek FDA approval through the 505(b)(2) regulatory pathway and briefly describe its implications.

<u>Risk Factors</u> <u>Risks Related to Our Business</u> <u>Clinical drug development involves a lengthy and expensive process ...," page 14</u>

7. The additional risks relating to conducting COR.1 and a portion of COR.2 outside the United States are distinct from the other risks described in this disclosure. Please discuss these risks in an independent risk factor under an appropriate sub-caption.

"If we are unable to differentiate Hydros-TA from steroid injections ...," page 17

8. Similarly, the risk relating to generic competition is distinct from that described in the remainder of this risk factor. Please address the generic risk in an independent risk factor and remove references to it from this one.

"If product liability lawsuits are brought against us . . .," page 21

9. Please amend this risk factor to include the maximum limit of your product liability insurance coverage.

"If we are not successful in attracting and retaining highly qualified personnel ...," page 22

10. Please amend this risk factor to include the name(s) and title(s) of the personnel whose departure has the possibility of creating a material adverse effect.

Use of Proceeds, page 51

- 11. Please amend your disclosure to state whether you believe you will be able to complete both the COR1.1 and COR1.2 clinical trials using your offering proceeds.
- 12. Please separate the amount of offering proceeds you expect to allocate toward research and discovery efforts from the remainder that you anticipate directing toward working capital and general corporate purposes.

Management's Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Policies and Significant Judgments and Estimates Revenue Recognition, page 70

13. You disclose on page 58 that you are eligible to receive regulatory and commercial milestone payments under the Shanghai Jingfeng Agreement. Please revise to disclose your accounting policy for milestones here and in Note 2 to the financial statements. Refer to ASC 605-28-50-1.

Stock-based Compensation, page 72

14. Please note we may have additional comments on your accounting for stock-based compensation or any beneficial conversion features once you have disclosed an estimated offering price. Please provide us with a quantitative and qualitative supplemental analysis explaining the difference between the estimated offering price and the fair value of each equity issuance through the date of effectiveness for the preceding twelve months.

Business Overview, page 76

15. We note your disclosure that Hydros is currently in a pre-clinical phase while TA has been cleared to proceed along the 505(b)(2) pathway. Please amend your disclosure to clarify, if true, that in order to obtain regulatory approval of Hydros-TA, Hydros does not have to undergo any clinical testing independent of the studies you have completed and intend to perform on Hydros-TA.

Our Solution - Hydros-TA, page 80

- 16. Please explain the significance of Hydros-TA being comprised of both soluble HA and a three-dimensional HA hydrogel component, particularly since it is apparently the HA hydrogel component that is retained in the joint for longer periods.
- 17. In your discussion of the COR1.0 Phase 2b trial, it appears that 60 of the patients were removed from the study as a result of the screening process. Please provide examples of reasons why a possible subject would have been eliminated from the study after having been screened.

18. Please provide examples of the reasons why certain subjects who were administered Hydros-TA and Synvisc-One did not complete the COR1.0 trial.

Intellectual Property, page 92

19. Please amend your disclosure to describe the various conditions under which both you and Shanghai Jingfeng Pharmaceutical Co., Ltd. may terminate your technology license agreement.

<u>Financial Statements</u> <u>Notes to Financial Statements</u> <u>5. License Agreement with Shanghai Jingfeng Pharmaceutical Co. Ltd., page F-18</u>

- 20. Regarding your Agreement with Jingfeng, please explain to us your basis for recognizing the upfront license payment upon signing the Agreement in November 2012. Tell us how the License meets the standalone value criteria under ASC 605-25-25-5a. Include in your response the following additional information:
 - Explain to us how Jingfeng has the ability to exploit the license without receiving the Services the Company has agreed to provide under the Agreement. Also you disclose on page 64 that the regulatory milestone received in November 2013 was a technology license fee and disclose on page 92 that in November 2013, "we received a non-refundable milestone payment related to the completion of the initial transfer of technology of \$0.4 million". Explain to us how the initial license provided everything necessary for Jingfeng to use the license for its intended purpose without receiving these undelivered items;
 - You disclose on page F-19 that Jingfeng can sublicense its rights to the License for a reasonable amount of consideration. Tell us why the rights to sublicense are limited to a reasonable amount of consideration;
 - Explain to us how your allocation of the November 2013 regulatory milestone payment between the License and the Services complies with the applicable accounting literature;
 - Please provide the disclosure required by ASC 605-28-50-2 for this arrangement; and
 - Explain to us your basis under GAAP for recognizing revenue net of the Chinese withholding tax and tell us if the tax is reclaimable.

6. Loan and Security Agreement, page F-20

21. Please provide us with your analysis under ASC 470-50 to support why the amendment to the Loan and Security Agreement in February 2013 was accounted for as a modification and not an extinguishment.

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 Donald Abbott at (202) 551-3608 or Mary Mast at (202) 551-3613 if you have questions regarding comments on the financial statements and related matters. Please contact Scot Foley at (202) 551-3383, 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: David J. Saul, Esq. Ropes & Gray LLP 1900 University Ave., 6th Floor East Palo Alto, CA 94303