



DIVISION OF  
CORPORATION FINANCE

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

January 8, 2015

Via E-mail

John Simard  
Chief Executive Officer  
XBiotech, Inc.  
8201 E. Riverside Drive  
Building 4, Suite 100  
Austin, TX 78744

**Re: XBiotech, Inc.  
Confidential Draft Registration Statement on Form S-1  
Submitted December 10, 2014  
CIK No. 0001626878**

Dear Mr. Simard:

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.

Prospectus Summary  
Our Business, page 1

1. Please briefly explain the requirements and function of the FDA's fast track designation where you initially reference it in the summary.
2. Please disclose in the prospectus summary whether your "True Human" monoclonal antibodies are licensed or were developed in-house. If developed in-house, please clarify the extent to which the proprietary technology underlying your discovery platform and manufacturing systems are based upon licensed technology. You should file any material licenses as exhibits, describe the related agreements in the business section, and identify

all licensed intellectual property as such under your “Intellectual Property” heading on page 57.

3. In the pipeline table on page 2, you indicate that you have tested your product candidate in the indication of leukemia in Phase 1 clinical trials. Your disclosure is unclear regarding whether you have any current plans to further pursue this indication. Please tell us why leukemia appears in the pipeline table and disclose any plans you have to advance the product candidate for this indication. If you have no such plans, you should eliminate the indication from the table.

#### Risk Factors

“Even if this offering is successful....” page 9

4. In the first paragraph on page 10, you disclose that you expect the proceeds from this offering will be sufficient to fund your current operations for at least the next 30 months. On page 41, however, you disclose that your current cash and cash equivalents together with the proceeds from this offering will be sufficient to fund you through the next 12 months. Please reconcile these two disclosures.

#### Use of Proceeds, page 32

5. On page 37, you disclose that you intend to continue your Phase II study in pyoderma gangrenosum and that you plan to conduct a clinical study for your antibody therapy for *S. aureus* infections, both in 2015. If you plan to allocate a material portion of the proceeds from this offering to either of these studies, you should disclose the respective amounts in your use of proceeds section. Please also disclose how far you expect the application of these proceeds will allow you to progress in each study.

#### Management’s Discussion and Analysis

Research and Development Expenses, page 36

6. Please disclose the total research and development expenses incurred from inception to date.

#### Critical Accounting Policies

Stock-Based Compensation, page 38

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

Foreign Currency Fluctuations, page 42

8. We note your reference here to a description of the effect of foreign currency fluctuations in the “Quantitative and Qualitative Disclosure of Market Risks” section. However, we are unable to locate this information. Please revise your disclosures as necessary. Refer to Item 305(a) of Regulation S-K.

Business

US Registration Study Oncology, page 46

9. Please disclose whether you have filed an Investigational New Drug (IND) application for the indication of colorectal cancer. If no IND has been filed, please tell us why.

Phase II study Pyoderma Gangrenosum (PG), page 47

10. Please disclose where you are conducting this study and whether you have filed an Investigational New Drug (IND) application for this specific indication. If no IND was filed, please tell us why.
11. You briefly discuss interim findings from this study to date, disclosing that several patients experienced improved wound healing. You should disclose all material results observed in this study. Your expanded disclosure should include the incidence and type of any treatment-related adverse effects observed, the total number of patients treated, and how you assessed improved wound healing in determining whether the study met the primary efficacy endpoints.
12. Your disclosure on page 37 indicates that you plan to continue the Phase II program for PG in 2015. Please disclose, to the extent known to you, the location, design, and goals of the next Phase II study for this indication.

Non-Small-Cell Lung Cancer (NSCLC), page 48

13. Please expand the description of this study to include a complete discussion of the study’s location, design, and results. For example, you should disclose whether this was a randomized controlled study and disclose any p-values observed. Where you reference the “control population in the Tarceva study,” please add a qualifier to indicate, if true, that you refer to a historical control group. Please additionally disclose whether you have filed an IND application for this specific indication. If no IND application was filed, please tell us why.

Colorectal Cancer, page 50

14. Please expand the description of this study to include a complete discussion of the study’s location, design, and results. For example, you should disclose whether this was a

randomized controlled study and disclose any p-values observed. Where you reference the treatment with Regorafenib, please add a qualifier to indicate, if true, that you refer to a historical control group, and please add disclosure indicating the limitations inherent in comparing the results of this study with a historical control.

Anorexia/Cachexia, page 50

15. Please define the term “cachexia” the first time you use it in this section.

Cardiovascular Disease, page 52

16. Please disclose where you conducted this study and whether you have filed an Investigational New Drug (IND) application for this specific indication. If no IND was filed, please tell us why.

Psoriasis, page 53

17. Please expand the description of this study to include a complete discussion of the study’s location, design, and results. For example, you should disclose whether this was a randomized controlled study, disclose any p-values observed, and disclose the number of patients treated. Please additionally disclose whether you have filed an IND application for this specific indication. If no IND application was filed, please tell us why.

Acne, page 53

18. Please expand the description of this study to include a complete discussion of the study’s location, design, and results. For example, you should disclose whether this was a randomized controlled study, disclose any p-values observed, and disclose the number of patients treated. Please additionally disclose whether you have filed an IND application for this specific indication. If no IND application was filed, please tell us why.

Diabetes (Type 2), page 53

19. Please expand the description of this study to include a complete discussion of the study’s design and results. For example, you should disclose whether this was a randomized controlled study, disclose any p-values observed, and disclose the number of patients treated. Please additionally disclose whether you have filed an IND application for this specific indication. If no IND application was filed, please tell us why.

Intellectual property, page 57

20. You disclose that you currently have 36 issued patents in various countries. Please disclose;

- the specific jurisdictions covered by your issued patents,

- the protection your issued patents afford (e.g., composition of matter, method of treatment, etc.), and
- the expiration dates.

Competition, page 63

21. Please identify the specific competitors currently developing human antibodies for treatment of cancer, diabetes, cardiovascular disease, psoriasis, pyoderma gangrenosum, and acne, and disclose the progress of those competitors toward a marketed product, to the extent known to you.

Executive Compensation, page 72

22. Please provide the disclosure required by Item 402(m)-(r) of Regulation S-K for your two most highly compensated executive officers other than Mr. Simard. Please note that your “significant employees” disclosed on page 64 may qualify as executive officers according to the definition of an executive officer contained in Exchange Act Rule 3b-7. Alternately, if none of your other employees’ total compensation met the threshold contained in Instruction 1 to Item 402(m)(2), please advise.
23. In your description of the terms of the employment agreement with Mr. Simard in this section, you disclose that his current annual base salary is set at \$550,000. However, both the employment agreement attached as exhibit 10.1 and the summary compensation table indicate that his annual salary is \$240,000. Please reconcile the apparent discrepancy.

Ownership of Certain Beneficial Owners and Managements, page 75

24. In footnote 3 to your beneficial owners table, please identify the natural person who holds sole or shared beneficial ownership of the shares hold by Haywood Securities.

Underwriting, page 96

25. You disclose that the underwriters are committed to purchase all of the shares of common stock offered by the prospectus if any of the shares are purchased. On page 100, however, you disclose that the shares are being offered on a best efforts, minimum/maximum basis. Please revise your disclosure to clearly indicate whether the OpenIPO process will be conducted on a firm commitment or a best efforts basis.

The OpenIPO Auction Process, page 97

26. We note references throughout this section to selling shareholders. Please explain to us the role that these selling shareholders will play in the auction process and explain how they received or will receive shares to be sold in the offering. We may have further

comment. Additionally, as to any selling shareholders, you should provide the disclosure in your prospectus required by Item 507 of Regulation S-K, and you should separately state the amount of securities offered by selling shareholders on the outside front cover page of the prospectus in accordance with Item 501(b)(2) of Regulation S-K.

27. You state that “some selected dealers” in addition to WR Hambrecht may conduct the auction process and confirm bids from prospective investors. Please confirm that you plan to identify these other dealers as underwriters in a future pre-effective amendment. Please additionally confirm that all underwriters’ procedures will uniformly follow the procedures laid out in this section. If not, you should describe all material differences in procedure as to each underwriter. Regardless, if you intend to use multiple underwriters to facilitate the auction, you should submit a letter in which WR Hambrecht represents that each underwriter agrees to offer the shares in accordance with the procedures described in the prospectus.
28. Please tell us whether WR Hambrecht or any other underwriters who will participate in the auction will impose any account-funding requirements on prospective investors that are specific to this offering. We may have further comment.
29. You disclose that investor funds received prior to closing will be wired to an escrow account for the benefit of investors and returned to investors if insufficient funds are received at closing. Please confirm that you will file the escrow agreement as an exhibit to your registration statement as soon as it becomes available.

#### Notes to Consolidated Financial Statements

##### 11. Subsequent Events, page F-23

30. We note you entered into a licensing agreement with STROX Biopharmaceuticals, LLC, for which you paid \$30,000, issued 50,000 options and agreed to pay a royalty on net sales. Please disclose your accounting policy for the transactions related to this agreement, including the value you ascribed to the options and where the transactions are recorded in your financial statements. Refer to ASC 808.10.50.1.

#### Other Comments

31. Please submit all outstanding exhibits as soon as practicable. We may have further comments upon examination of these exhibits.
32. 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.
33. 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.

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 Rolf Sundwall at (202) 551-3105 or Sharon Blume at (202) 551-3474 if you have questions regarding comments on the financial statements and related matters. Please contact Austin Stephenson at (202) 551-3192 or me at (202) 551-3715 with any other questions.

Sincerely,

/s/ Jeffrey P. Riedler

Jeffrey P. Riedler  
Assistant Director

cc: Via E-mail  
R. Hector MacKay-Dunn, Esq.  
Farris, Vaughan, Wills & Murphy LLP