Quarles & Brady LLP

1395 Panther Lane
Suite 300
Naples, Florida 34109
239.262.5959
Fax 239.434.4999
www.quarles.com

Attorneys at Law in
Chicago
Indianapolis
Madison
Milwaukee
Naples
Phoenix
Scottsdale
Tampa
Tucson
Washington, D.C.

Writer's Direct Dial: 239.434.4905
E-Mail: laura.holm@quarles.com

March 27, 2015

Jeffrey P. Riedler, Assistant Director
Division of Corporation Finance
Securities and Exchange Commission
Washington, D.C. 20549

Re: XBiotech Inc.
Amendment No. 1 to Registration Statement on Form S-1
Filed March 10, 2015
File No. 333-201813

Dear Mr. Riedler:

On behalf of XBiotech Inc. (the "**Company**"), set forth below are the Company's responses to the comments of the staff (the "**Staff**") of the Securities and Exchange Commission ("**SEC**") received by letter dated March 24, 2015 relating to the Company's Amendment No. 1 to the Registration Statement on Form S-1 submitted to the SEC on March 10, 2015.

The Company is concurrently filing via EDGAR Amendment No. 2 to the Registration Statement ("**Amendment No. 2**") which reflects the Company's responses to the comments received by the Staff and certain updated information.

In this letter, we have recited the comments from the Staff in italicized type and have followed each comment with the Company's response. Except as otherwise specifically indicated, page references herein correspond to the page of Amendment No.2, as applicable.

General

1. *We note your response to our prior comment 1 and the letter you supplementally provided on March 19, 2015. Please file the form of any subscription agreement that you intend to use in connection with this offering as an exhibit to the registration statement.*

Response:

The Company is not using a subscription agreement in this offering.

Business
Current Clinical Investigation Activity
US Registration Study Oncology, page 55

2. *We note that you halted your Phase III oncology study using Xilonix, eliminated certain criteria for inclusion in the study and amended the nature of the control arm. Please include the following in your disclosure:*

briefly describe the new control arm;

The new study design is a double blind, randomized, placebo controlled trial of Xilonix plus best supportive care versus placebo plus best supportive care. The patients in the control arm will receive an infusion of placebo every 2 weeks until tumor progression. Both the active and control arms receive "best supportive care", however therapies with a proven anti-cancer benefit or investigational therapies are forbidden for patients on trial. [NCT01767857]

☐ *state whether there was a change in the indication being studied, and if so, describe the original and the revised indication;*

Yes, a change in indication was proposed, which eliminated the weight loss criteria. The original indication was "patients with colorectal cancer and cachexia."(Protocol Version 2.4) The subjects under the original indication were colorectal cancer patients who had lost >5% of their total body weight in the previous six months. The new indication set forth in a Protocol Amendment (Protocol Version 3.0) submitted to the FDA on May 27, 2014 modified the indication to "patients with refractory colorectal cancer," which in most cases includes some amount of weight loss. In all other respects the target population for the original and new indication are essentially the same.

☐ *describe the facts and circumstances prompting the halting of the study and the changes that were made to the study;*

During the first year of screening, subjects in the approved Phase III study, investigative sites struggled to enroll colorectal cancer patients that had lost >5% of their total body weight in the previous 6 months. After a year of screening, only 40 patients were enrolled, while over 300 had been excluded for not meeting the study inclusion criteria. The Company was of the opinion that the inclusion criteria related to the cachexia indication was impeding study progress. Therefore, the Company submitted an amendment to the current study (Protocol Version 2.4) and modified the indication being studied (Protocol Version 3.0). In addition, due to positive safety data reports generated from the multicenter Phase III study conducted by the Company in the European Union at a dosing regime of 7.5 mg/kg, the protocol amendment included a modification to the dosing regime to increase dosing from 3.75 mg/kg (the dosage approved in Protocol Version 2.4) to 7.5 mg/kg (the dosage proposed in the amendment Protocol Version3).

XBiotech submitted the amended protocol, Protocol Version 3 to the FDA on May 27, 2014. On July 10, 2014, a teleconference between the Division of Oncology Products 2 and XBiotech was held to discuss changes to Protocol Version 3, as well as manufacturing changes to the cell line being proposed. During this conference call, the

FDA informed XBiotech that it had not established a maximum tolerated dose of 7.5 mg/kg in any studies under the FDA's jurisdiction. Therefore, a partial clinical hold was placed on the Protocol Version 3 (not yet initiated), and the FDA reasoned that since the Company was no longer pursing the cachexia indication, future enrollment of additional patients to the study conducted under Protocol 2.4 after July 10, 2014 would be of no benefit in support of a drug approval. The FDA did not put a hold on subjects who had already been enrolled in the study who were receiving 3.75mg/kg of the investigative agent on this trial or other trials currently ongoing under other INDs. The FDA's partial hold was in no way related to concerns about the current dosing level of subjects at 3.75 kg/mg; rather the hold was to address the need for additional safety data that related to the proposed dose escalation, and changes to the protocol related to the amended indication.

Based on the July 10, 2014 call with the FDA, the Company contacted each of the investigators at the investigative sites on July 10, 2014 to communicate that a voluntary enrollment hold was in effect and to stop further randomization of subjects at the 3.75 mg/kg dosing regime. On July 16, 2014 a teleconference between the Company and the investigative sites took place. At that time, the Company again reiterated that it was voluntarily stopping further enrollment of subjects at the 3.75 dosage under Protocol 2.4 as the resulting data would not be utilized to support the marketing authorization of the product due to the proposed amendment under Protocol 3.0.

☐ *discuss the FDA's role in this process and the dates and substance of all communications between the registrant and the FDA; and*

On January 20**,** 2014, the Company submitted a protocol detailing the comparability of the new cell line used to produce the monoclonal antibody MABp1 with the previous cell line.

On May 27, 2014, the Company submitted an amended Protocol Version 3 that modified the indication of use, and proposed an increase in the dosage from 3.75 mg/kg to 7.5 mg/kg. In addition, an annual IND safety report and updated Investigator Brochure was submitted.

On July 9, 2014**,** the Company and FDA corresponded regarding the teleconference to discuss the clinical questions related to the amendment (Protocol 3.0) to the Protocol Version 2.4.

On July 10, 2014, the Company's CEO, CMO, and representatives from Chemistry Manufacturing Control, Quality and Biostats attended a call with representatives of the FDA's Division of Oncology Products 2. During the call the FDA issued a partial hold as discussed above for future subjects until additional safety information was provided related to maximum tolerated dose of 7.5 mg/kg in any studies under the FDA's jurisdiction. In addition, the discussion included FDA's request for additional information related to the chemistry, manufacturing and controls of the new cell line.

On July 14, 2014 the FDA requested a teleconference with the Company to obtain clarifying information related to the agents being used in current studies and data that exists related to adventitious agent testing.

On July 15, 2014 the Company had a teleconference with FDA in which the agency requested additional information related to the method of selecting the clone for the new cell line.

In an FDA Letter dated August 1, 2014, the FDA stated that the IND was on partial clinical hold due to insufficient information to assess risks to human subjects and unreasonable and significant risk of illness or injury to human subjects related to the dose escalation to 7.5 mg/kg. As noted, the insufficient information related to Protocol Version 3 (which had not yet been initiated),

On August 15, 2014, the Company submitted a response to the FDA letter dated August 1, 2014 that addressed the August 1 concerns.

On August 20, 2014, the FDA reviewed the response to the clinical hold received on August 15, 2014 and had additional questions, which were answered by the Company on August 25th.

In a letter dated September 10, 2014, the FDA indicated that the Company could resume enrollment of new patients in Protocol 2012-PT023, version 2.4 or 3 at a dosage of 7.5mg/kg under the new indication.

☐ *state whether or not you obtained a special protocol assessment.*

XBiotech did not request a special protocol assessment (SPA), as the FDA's non-hold questions included review of the amended protocol design, inclusion, endpoints, and statistical analysis plan. Thus while not dubbed an SPA, the protocol review process was in essence a protocol assessment.

Please also supplementally provide us with your communications with the FDA in connection with this study. Please note that you may request that these materials be returned to you after completion of our examination in accordance with Rule 418.

We have complied with the Staff's request to provide this information on a supplemental basis.

Other Commercial Agreements, page 64

3. We note your response to our prior comment 7. Please revise your disclosure regarding your agreements with Lonza Sales AG and South Texas Blood & Tissue Center to disclose the potential range of royalty payments (for example, "low-single-digits", "high-single-digits" or a range not to exceed ten percent).

We have revised the disclosure to indicate that the royalty payments with Lonza Sales AG and South Texas Blood & Tissue Center are in the "low-single digits."

* * * * * *

Thank you for your consideration. Please direct your questions or comments regarding the Company's responses to the undersigned at (239) 434-4905 or laura.holm@quarles.com. Thank you for your assistance.

Sincerely,

Quarles & Brady LLP

/s/ Laura M. Holm

Laura M. Holm

Enclosures

cc (w/encl.) John Simard, Chief Executive Officer
XBiotech Inc.

James R. Tanenbaum, Esq.
Morrison & Foerster LLP