XBiotech Inc.
Form 8-K
December 16, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): December 16, 2016

XBIOTECH INC.
(Exact name of Registrant as specified in its charter)

British Columbia, Canada
(State of Incorporation)

001-37347
(Commission File Number)

N/A

(I.R.S. Employer Identification No.)

8201 E Riverside Dr. Bldg 4, Ste 100

78744

Austin, Texas

(Zip Code)

(Address of principal executive offices)

(512) 386-2900

(Registrant’s telephone number, including area code)

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01 Other Events.

On December 16, 2016, XBiotech Inc. (the “Company”) announced that it has received the Day 180 List of Outstanding Issues (the “LoOIs”) from the European Medicines Agency’s (“EMA”) Committee for Medicinal Products for Human Use (the “CHMP”) in connection with the Company's Marketing Authorization Application (the “MAA”) for Xilonix. Xilonix is an investigational drug candidate being evaluated for the treatment of advanced colorectal cancer.

Major objections remain relating to clinical and quality matters. Clinical objections pertain primarily to benefit risk justification of the therapy and pharmacokinetics. Quality objections relate to qualification of the cell line used to produce the antibody and scaled down systems used to demonstrate robustness of the purification process as well as clarification of critical process controls. No objections remain regarding non-clinical aspects of the application. The Company believes the CHMP’s requests are addressable. The Company plans to submit its responses to the LoOls within 60 days, in line with an updated regulatory timetable.

This Form 8-K and related presentation contains forward-looking statements, including declarations regarding management's beliefs and expectations, that involve substantial risks and uncertainties. In some cases, you can identify forward-looking statements by terminology such as “may,” “will,” “should,” “would,” “could,” “expects,” “plans,” “contemplate,” “anticipates,” “believes,” “estimates,” “predicts,” “projects,” “intend” or “continue” or the negative of such terms or other comparable terminology, although not all forward-looking statements contain these identifying words. Forward-looking statements are subject to inherent risks and uncertainties in predicting future results and conditions that could cause the actual results to differ materially from those projected in these forward-looking statements. Applicable risks and uncertainties include the risks that the interim data from this clinical trial may not be predictive of the results from the completed clinical trial, that the Company will be unable to successfully complete this clinical trial by year end and the other disclosures set forth in "Risk Factors" in our SEC filings.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: December 16, 2016 XBIOTECH INC.

By: /s/ John Simard
John Simard
Chief Executive Officer and President