

XBiotech Inc.
Form 8-K
February 08, 2017

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): February 8, 2017

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 February 8, 2017, XBiotech Inc. (the “Company”) announced that it has been granted more time to submit its responses to the Day 180 List of Outstanding Issues (the “LoOIs”) by 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.

The Company was granted an additional 30 days to submit its responses, extending the “clock-stop” period to March 22, 2017. This extension will allow sufficient time for the Company to complete a pharmacokinetic (“pk”) study in healthy subjects. Data from this study is intended to generate additional time points for pk analysis. These findings are intended to address the relevant LoOIs and will be included in the Company’s response submission scheduled for March 22nd.

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: February 8, 2017 XBIOTECH INC.

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