

XBiotech Inc.
Form 8-K
April 21, 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): April 20, 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
Austin, Texas
(Address of principal executive offices)

78744
(Zip Code)

(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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter)

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 Other Events.

Outcome of EMA Oral Explanation Meeting

On April 20, 2017, XBiotech Inc. (the “Company”) issued a press release announcing the outcome of its Oral Explanation meeting (“OE”) to discuss its Day 180 List of Outstanding Issues related to the Company’s Marketing Authorization Application submission for its lead product candidate in Europe. The Company reported that the European Medicines Agency (“EMA”) rendered a negative “trend” vote after the meeting, making a positive Committee for Medicinal Products for Human Use (“CHMP”) opinion unlikely. At the OE the Company gave a 20 minute presentation and had a Q&A session with CHMP members per standard meeting protocol.

A copy of the press release issued in connection with the announcement is filed as Exhibit 99.1 to this Current Report on Form 8-K. A copy of the presentation is filed as Exhibit 99.2 to this Current Report on Form 8-K.

This Form 8-K and the related press release contain 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 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. These risks and uncertainties are subject to the disclosures set forth in “Risk Factors” in our SEC filings.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit

Description

Number

99.1 Press Release of XBiotech Inc., Issued April 20, 2017.

99.2 Oral Explanation Presentation Slides

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: April 20, 2017 XBIOTECH INC.

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