# UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

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## 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): May 24, 2016

## XBIOTECH INC.

(Exact Name of Registrant as Specified in Charter)

**British Columbia Canada** 

(State of Incorporation)

001-37347

(Commission File Number)

N/A

(IRS 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))

## Item 8.01. Other Events.

On May 24, 2016, XBiotech Inc. (the "Company"), issued a press release announcing its plan to present survival data for Xilonix<sup>TM</sup>, the Company's lead therapy developed for the treatment of advanced colorectal cancer, at the European Society of Medical Oncology's World Congress on Gastrointestinal Cancer, on July 1, 2016, in Barcelona, Spain. A copy of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

On May 18, 2016, XBiotech gave a business update via telephone conference call. An audio webcast of the call will be available on the Investors relations section of the XBiotech website at investors.xbiotech.com. The webcast will be archived for 90 days.

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

## Item 9.01. Financial Statements and Exhibits.

- (d) Exhibits.
- 99.1 Press Release of XBiotech Inc., issued May 24, 2016

## SIGNATURE

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.

## XBIOTECH INC.

Date: May 24, 2016

By: \( \frac{15}{2} \) John Simard

Name: John Simard

By: <u>/s/ John Simard</u>
Name: John Simard
Title: Chief Executive Officer and President

## EXHIBIT INDEX

Exhibit Number Description

99.1 Press Release, issued May 24, 2016

## XBiotech to Present Positive Preliminary Survival Data on Xilonix™ at the 18th European Society of Medical Oncology's World Congress on Gastrointestinal Cancer

- First Time Pivotal Phase III Xilonix Data to be Unveiled at Major Scientific Congress, Including Positive Preliminary Overall Mean Survival Data for Responders
- Developed Specifically to Treat Advanced Cancer, Xilonix is First Antibody Therapy to Neutralize Biological Activity of Interleukin-1α (IL-1a)
- Xilonix Recently Granted Accelerated Review for Marketing Authorization by the European Medicines Agency (EMA); a decision on Xilonix approval could come as
  early as fourth quarter 2016

AUSTIN, Texas, May 24, 2016 (GLOBE NEWSWIRE) -- XBiotech Inc. (NASDAQ:XBIT), developer of next generation True Human<sup>TM</sup> antibody therapies, today said its upcoming presentation of pivotal Phase III data for Xilonix<sup>TM</sup>, the Company's lead therapy developed for the treatment of advanced colorectal cancer, will include positive preliminary findings on survival. The data are being presented July 2 at the  $18^{th}$  ESMO World Congress on Gastrointestinal Cancer in Barcelona, Spain.

This will be the first presentation of the Phase III data at a major scientific congress. The primary endpoint of the study was clinical response rate (CRR) after 8 weeks of therapy in patients with advanced disease and multiple symptoms known to inversely correlate with overall survival. The CRR criteria were developed in collaboration with EMA's Scientific Advice Working Group to assess anti-tumor benefit of therapy based on control of these symptoms. Secondary endpoints evaluated paraneoplastic thrombocytosis and systemic inflammation, which also are known correlates for survival in colorectal cancer. As specified in the Phase III protocol, investigators also followed up with patients after study completion or discontinuation to assess their survival status. XBiotech will share positive preliminary results from this analysis showing a survival benefit correlating to the clinical response seen in this trial; this analysis is ongoing.

A potential breakthrough for patients with advanced colorectal cancer, Xilonix is specifically designed to target and neutralize interleukin-1 alpha (IL-1a), a molecule known to promote angiogenesis (the growth and spread of tumors), as well as mediate symptoms such as metabolic dysregulation (e.g., a cause of muscle loss and weight loss), fatigue and anxiety associated with advanced cancer.

The abstract, entitled "A Pivotal Phase III Trial of Xilonix in Advanced Colorectal Cancer," will be presented by Dr. Tamas Hickish, Chair of the Xilonix European Phase III Study, and Consultant Medical Oncologist, Royal Bournemouth Hospital NHS Foundation Trust, UK. Colorectal cancer is the leading cause of malignancy in the industrialized world.

## About True Human™ Therapeutic Antibodies

Unlike previous generations of antibody therapies, XBiotech's True Human™ antibodies are 100 percent human, derived from individuals who possess natural immunity to certain diseases. With discovery and clinical programs across multiple disease areas, XBiotech's True Human antibodies have the potential to harness the body's natural immunity to fight disease with increased safety, efficacy and tolerability.

The first of these therapies, Xilonix<sup>TM</sup>, for advanced colorectal cancer, is in Phase III clinical trials in the United States with a Fast Track designation by the U.S. Food and Drug Administration (FDA). In Europe, Xilonix Phase III clinical trials have been completed, and the therapy is under accelerated review following the validation of its Market Authorization Application by the European Medicines Agency (EMA).

#### About XBiotech

XBiotech is a fully integrated global biosciences company dedicated to pioneering the discovery, development and commercialization of therapeutic antibodies based on its True Human™ proprietary technology. XBiotech currently is advancing a robust pipeline of antibody therapies to exceed the standards of care in oncology, inflammatory conditions and infectious diseases. Headquartered in Austin, Texas, XBiotech also is leading the development of innovative biotech manufacturing technologies designed to more rapidly, cost-effectively and flexibly produce new therapies urgently needed by patients worldwide. For more information, visit www.xbiotech.com.

## Cautionary Note on Forward-Looking Statements

This press release 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. These risks and uncertainties are subject to the disclosures set forth in the "Risk Factors" section of certain of our SEC filings. Forward-looking statements are not guarantees of future performance, and our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate, may differ materially from the forward-looking statements contained in this press release. Any forward-looking statements that we make in this press release speak only as of the date of this press release. We assume no obligation to update our forward-looking statements whether as a result of new information, future events or otherwise, after the date of this press release.

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