

**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) July 1, 2015

XBIOTECH INC.

(Exact name of registrant as specified in its 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))
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Item 8.01. Other Events.

On July 1, 2015, XBiotech Inc. (the "Company"), announced that it held an investigators meeting to update clinicians and support staff on the overall status of the Company's Phase III study in colorectal cancer which is being conducted outside of the United States. The Company is conducting a double-blinded, placebo-controlled registration study of its anticancer agent for the treatment of advanced colorectal cancer. The novel anti-cancer agent, Xilonix™, is being developed with a regulatory path that the Company established in collaboration with the scientific advisory committee of the European Medicines Agency ("EMA"). The data presented to investigators at the meeting summarized the major findings of this clinical study to date. Although the study was not unblinded and only aggregate data were presented, physicians and support staff involved in the study were given an opportunity to gain a better sense of the overall patient performance.

The following data were presented:

A total of 220 patients were reported to be currently enrolled in the study. Data were provided relating to patient performance in the study. As of June 15, 2015, the company stated that 183 patients had completed at least one cycle of therapy and 98 patients had baseline and follow-up DEXA and EORTC-QLQc30 data available. It was also reported that 35 patients had dropped out before completing the 8-week treatment regimen, while there were a further 50 patients at various stages of the 8 week treatment regimen. The Company reported that 61 patients (62% of evaluable patients) were considered to have a positive DEXA outcome as defined for the responder endpoint, with an average Lean Body Mass (LBM) change of 2.1 ± 2.8 kg (median 1.2 [IQR 0.5 to 2.0] kg). At the time of analysis, there were also 59 patient responders (60% of evaluable patients) according to the EORTC responder definition. There were 93 patients evaluable for RECIST, which included 2 partial responses (PR) and 23 patients with stable disease (SD). The study was also said to be on schedule for completion as planned this year.

DEXA, or dual-energy X-ray absorptiometry, is a type of X-ray machine that can measure body compartments, and distinguish between bone, fat and lean tissue (i.e. muscle). The DEXA can thus be used to measure non-fat weight gain in patients. EORTC-QLQ30 is a validated questionnaire developed in Europe that is used to accurately record patient reported health status, such as levels of fatigue, pain and appetite. A DEXA and EORTC performance composite was used to identify patient response to therapy. To be a responder individual patients must meet both DEXA and EORTC response criteria, which includes an increase in LBM from baseline to week 8 as well as improvement or no worsening in 2 of 3 symptoms as measured by the EORTC questionnaire. The study has been designed to compare responders in the treatment arm versus the placebo.

A copy of the Company's press release announcing the foregoing is attached as Exhibit 99.1

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. 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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.
99.1 Press Release of XBiotech Inc., issued July 1, 2015

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.

(Registrant)

/s/ **JOHN SIMARD**

July 1, 2015

(Date)

John Simard

Chief Executive Officer and President

EXHIBIT INDEX

Exhibit
Number

Description

99.1 Press Release, issued July 1, 2015

XBiotech Conducts Investigators Meeting to Update the Status of Its Phase III Registration Study Underway in Europe

AUSTIN, Texas, July 1, 2015 (GLOBE NEWSWIRE) -- XBiotech (NASDAQ:XBITE), the developer of True Human™ therapeutic antibodies, announced today that it held an investigators meeting to update clinicians and support staff on the overall status of the Company's Phase III study in colorectal cancer. The Company is conducting a double-blinded, placebo-controlled registration study of its anticancer agent for the treatment of advanced colorectal cancer. The novel anti-cancer agent, Xilonix™, is being developed with a regulatory path that the Company established in collaboration with the scientific advisory committee of the EMA.

The potential breakthrough cancer drug is being evaluated under the EMA's "Guideline on Evaluation of Anticancer Medicinal Products in Man," which offers the possibility to establish novel approval endpoints for anti-cancer agents. In advanced cancer, historically only modest tumor responses are seen in a small percentage of the population. The EMA is thus seeking new endpoints and novel agents that will enable the evaluation of anti-tumor therapy based on patient recovery. Thus the EMA has proposed in its guidelines that, "In patients with tumour-related symptoms at baseline, symptom control, if related to anti-tumour effects, is a valid measure of therapeutic activity and may serve as primary endpoints in late line therapy studies."

The Company's Xilonix therapeutic monoclonal antibody targets the molecular signalling that leads to neoangiogenesis and other processes that support tumor vascularization and growth. However, the same molecular target is known to signal the brain to cause pain, fatigue, anxiety, appetite suppression and hypermetabolic syndrome seen in advanced cancer. Earlier observations of physical recovery that strongly correlated with improved overall survival were unprecedented findings with Xilonix therapy in advanced cancer patients. The results were published in April 2014 in *Lancet Oncology*. These findings positioned Xilonix to be able to take advantage of the EMA's unique regulatory pathway for anti-cancer drug development.

The data presented today to investigators summarized the major findings to date. Although the study was not unblinded and only aggregate data were presented, physicians and support staff involved in the study were given an opportunity to gain a better sense of the overall patient performance. The Company explained that the unprecedented nature of the study design means that physicians have little or no idea of what the overall expectations should be for study participants. The Company is providing the blinded data as requested so that physicians and other care givers may be better able to provide patients with expectations for overall outcomes, so that patients may be better informed when deciding whether to participate in this study.

The following data were presented:

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John Simard, XBiotech's CEO, stated, "The observation of recovery in advanced cancer patients treated with Xilonix made it an ideal therapy for us to work with the EMA to pioneer new endpoints for evaluating cancer therapy in advanced disease. It is widely recognized that in the presence of uncontrolled disease, symptom recovery cannot be anticipated. So the EMA's concept to develop cancer therapies around symptom recovery guides us towards developing anticancer agents that are better for the patient. I think this is tremendously insightful and a definite positive force for creating new and better therapies that keep the well being of cancer patients in mind. To date, however, due to toxicities of most agents, few anti-cancer therapies have been demonstrated to facilitate symptom recovery in a controlled study. Xilonix is thus at the crossroads of being a truly breakthrough anti-cancer agent that helps cancer patients feel better while treating their tumors, while Xilonix also sets a historic precedence for the way cancer therapies are conceived and evaluated in the clinic."

About XBiotech

XBiotech is pioneering a new era in the discovery and development of targeted antibodies based on its True Human™ technology. The company's mission is to rethink the way antibody medicines are discovered and commercialized by advancing its robust pipeline of *truly* natural human antibodies for treating serious diseases such as cancer, inflammatory conditions and infectious diseases. XBiotech's lead product, Xilonix™, is a potential breakthrough antibody therapy that is currently the subject of two pivotal clinical studies for treating patients with advanced colorectal cancer. Xilonix specifically targets and neutralizes interleukin-

1 alpha (IL-1a), a molecule known to promote angiogenesis, growth and spread of tumors, as well as mediate symptoms such as metabolic dysregulation, fatigue and anxiety associated with advanced cancer. XBiotech's broad pipeline of True Human antibodies is able to potentially deliver unmatched safety and efficacy because they are cloned directly from individual donors who possess natural immunity against certain targeted diseases. As such, True Human antibodies retain their natural physiology and tolerance profile, having passed the rigors of immune selection in the body. For more information, visit www.xbiotech.com.

CONTACT: Ashley Otero
XBiotech
aotero@xbiotech.com
512.386.2930

Tiberend Strategic Advisors, Inc.:
Joshua Drumm, Ph.D. (investors)
jdrumm@tiberend.com
212.375.2664

Janine McCargo (media)
jmccargo@tiberend.com
646.604.5150