XBiotech Inc.
Form 8-K
July 01, 2015

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

8201 E Riverside Dr. Bldg 4, Ste 100
Austin, Texas **78744**
(Address of principal executive offices) (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 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)

July 1, 2015

(Date)

/s/ JOHN SIMARD

John Simard
Chief Executive Officer and President

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press Release, issued July 1, 2015