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): January 8, 2016

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 **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:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 7.01 Regulation FD Disclosure.

Spokespersons of XBiotech Inc. (the "Company") plan to present the information contained in the document attached hereto as Exhibit 99.1 to various parties.

The furnishing of the attached file is not an admission as to the materiality of any information therein. The information contained in the document is summary information that is intended to be considered in the context of more complete information included in the Company's filings with the U.S. Securities and Exchange Commission (the "SEC") and other public announcements that the Company has made and may make from time to time by press release or otherwise. The Company undertakes no duty or obligation to update or revise the information contained in this report, although it may do so from time to time as its management believes is appropriate. Any such updating may be made through the filing of other reports or documents with the SEC, through press releases or through other public disclosures.

The information in this Item 7.01 of this Current Report on Form 8-K and Exhibit 99.1 attached hereto shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained in this Item 7.01 and in the presentation attached as Exhibit 99.1 to this Current Report shall not be incorporated by reference into any filing with the SEC made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 8.01 Other Events.

On January 7, 2016, XBiotech Inc. (the "Company"), issued a press release announcing that it planned to hold a public conference call and webcast to provide an overview of strategy and findings for its European Phase III trial for the treatment of colorectal cancer with Xilonix. The Company disclosed that the call will take place on Friday, January 8th at 8:30 a.m. ET and provided the following information on how to access the call:

Conference Call Information:
Interested participants and investors may access the conference call by dialing:

- 1 (877) 242-7960 (U.S.)
- 1 (330) 863-3267 (international)

An audio webcast will also be accessible via the Investors Relations section of the XBiotech website www.xbiotech.com/about/investors.html. The webcast replay will remain available for 90 days.

A copy of the Company's press release announcing the foregoing is attached as Exhibit 99.2 and is incorporated herein by reference.

On January 8, 2016, the Company issued a press release announcing and providing a summary on the additional positive findings from the Phase III European trial that will be discussed on the conference call scheduled for January 8, 2016 at 8:30 a.m. ET.

A copy of the Company's press release announcing the foregoing is attached as Exhibit 99.3 and is incorporated herein by reference.

This Form 8-K and the related Exhibits 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 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 Phase III Data Summary & Discussion Document
99.2 Press Release of XBiotech Inc., issued January 7, 2016
99.3 Press Release of XBiotech Inc., issued January 8, 2016

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: January 8, 2016

XBIOTECH INC.

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

EXHIBIT INDEX

Exhibit Number	Description
99.1	Phase III Data Summary & Discussion
99.2	Press Release of XBiotech Inc., issued January 7, 2016
99.3	Press Release of XBiotech Inc., issued January 8, 2016

Exhibit 99.1

Phase III Data Summary and Discussion

A Double Blind, Placebo Controlled, Pivotal Phase III Study Evaluating Xilonix™ in Symptomatic Colorectal Cancer Patients Refractory To Standard Therapy

08 January 2016

Clinical Protocol Synopsis

STUDY TITLE: A Double Blind, Placebo Controlled Pivotal Phase III Study Evaluating XILONIX™ in Symptomatic Colorectal Cancer Patients Refractory To Standard Therapy

Sponsor:

XBiotech Germany, GmbH.

Study Chair:

Tamas Hickish M.D.

Sample Size:

333 subjects.

Approximate Duration:

The duration of subject participation in the double blinded, placebo-controlled portion of the trial is approximately 77 days including a screening period of 14 days and a treatment/follow up period of 63 days. Subjects from both arms may continue treatment with Xilonix indefinitely in an open label extension, for as long as they are judged to be benefitting clinically and have had no unacceptable toxicities.

Methods

Primary Efficacy Endpoint

- The primary endpoint of this study is objective response rate (ORR). ORR is a composite measure, including change in lean body mass (LBM) and change in quality of life, as determined from screening to week 8. The ORR is defined as a stabilization or positive (≥0 kg) change in lean body mass (LBM) as assessed by dual-energy X-ray absorptiometry (DEXA) scan, and improvement or no worsening (≥0 score point change) on any two of the three symptom scale measures (fatigue, pain, appetite) of EORTC QLQ-C30.

Secondary Endpoints

- Secondary efficacy endpoints include measures of key cancer symptoms, as well as pharmacodynamics parameters. Parameters to be measured are: (1) change in functional scales and (2) global QoL as assessed by the EORTC QLQ-C30 questionnaire at screening and 8 week follow-up; (3) reduction in serum IL-6; and (4) stabilization of platelet count at 8 week compared to screening.
- Safety and tolerability of Xilonix as compared to placebo control.

Primary Analysis

The primary efficacy analysis was conducted on a modified intent to treat population. As defined in the protocol, this population included only those subjects who had been randomized and received at least a single dose of therapy. Subjects that consented to participate in the study and were randomized to a treatment arm but did not receive any infusion were not included in the data analysis.

Subjects that did receive at least one dose of placebo or drug were considered in the primary analysis. However, patients missing primary endpoint data, either at baseline or at follow-up, were considered to be non-responders. Additionally, subjects that receive explicitly restricted therapies (that would be expected to affect the assessment of the primary endpoint) were considered non-responders as well.

Ongoing quality assessment of the study included pharmacokinetic (pK) analysis of all patient blood samples. This analysis was performed by blinded quality control (QC) technicians using a validated assay. A single QC supervisor was unblinded during the study in order to record and confirm randomization of samples and perform pK analysis.

XBiotech adhered to the ICH Harmonised Tripartite Guideline Statistical Principles for Clinical Trials E9 guidelines (ICH-E9). Per ICH-E9 guidelines section 7.1, XBiotech will report on all subjects who entered the trial whether or not they are included in the primary analysis. Reasons for exclusion from analysis have been clearly stated and documented. For subjects included in the full analysis but not in the per protocol set, exclusion of these patients shall be based on objective criteria as recommended in section 5.2.1 of ICH-E9 guidelines regarding considerations for full analysis of data. With respect to errors relating to placebo-randomized patients that were in fact treated with the test article, the detection eligibility violations have been made objectively, without any bias through blinded technicians engaged in quality analysis.

The effect of all losses of subjects has been carefully considered. This includes comparing the primary efficacy analysis according to the modified intent plan with respect to an analysis using the most conservatively defined intent to treat population, where no patients are excluded from analysis (i.e. “n” equals the entire enrolled, randomized population including all those that received restricted therapy or those that did not receive any therapy whatsoever).

Results Summary

The primary endpoint analysis involves use of a novel objective response rate used to compare response rates between treatment and placebo arms (Table 1). Primary endpoint analysis was performed as described above using a modified intent to treat (mITT) analysis that included 309 patients (102 in placebo and 207 Xilonix). Twenty-four patients that received neither a dose of placebo nor test article were excluded from this analysis. Based on this mITT analysis, a total of 19 patients (19%) in the placebo group were considered responders, compared to 68 patients (33%) in the Xilonix arm (p=0.0045). These results represented a 76% relative improvement in response rate between the Xilonix and placebo arms respectively.

Secondary analysis performed in this study included key pharmacodynamic measures (Table 1b) that have been positively correlated with survival in advanced cancer patients and had been observed with the test article in previous clinical findings. A 5-fold increase in platelet counts observed in the placebo group compared to the treatment arm was significant (p=0.003), with platelet counts maintaining close to baseline levels with antibody therapy.

Although the study was not statistically powered to demonstrate differences in serious adverse events (SAEs) or stable disease between arms, these analyses are provided here due to the potential importance of these observations and the likely correlation between SAEs and the primary efficacy measure. A 26% relative risk reduction in the number of SAEs was observed in the treatment arm relative to placebo (p=0.062). Similarly, patients in treatment arm were 53% more likely to have stable disease (odds ratio 1.53 [95% CI 0.76 to 3.08]) compared to placebo at 8 weeks, although this difference did not reach statistical significance (p=0.12).

Table 1

Primary Efficacy Analysis	mITT Population (n=102 vs 207)					
	Placebo Responders (n)	Xilonix Responders (n)	Placebo Responders (%)	Xilonix Responders (%)	Relative Increase in Response Rate Xilonix	p Value
Responders	19	68	19%	33%	76%	0.0045

Table 1b

Secondary Analysis	Placebo	Xilonix	Placebo (%)	Xilonix (%)	Relative Change	p Value
Median Change in Platelet Counts (1,000/mm^3)	25	5	na	na	80% (relative magnitude reduction)	0.003
					Relative Improvement in Xilonix arm for Stable Disease (odds ratio)	
Patients with Stable Disease	12	35	12%	17%	53%	0.12
					Relative Risk Reduction Xilonix	
Number of Serious Adverse Events (SAE)	32	48	31%	23%	26%	0.062

RECIST V1.1. p values are for one-tailed significance testing.

Sensitivity Analyses: Intent to Treat Population

1. The most conservative data analysis includes ALL subjects randomized in a study without consideration for early dropouts, rapid progressors, or protocol violations. This population of patients is widely referred to as the Intent to Treat (ITT) population. Based on an ITT analysis, there were 68 patients in the Xilonix arm that were responders compared to 24 patients in the placebo group, representing 31% and 22% of patients in the arms, respectively (p=0.042). Secondary endpoints in the study showed an 80% relative reduction in magnitude of change in median platelet counts in the treatment arm compared to placebo (p=0.003). There were also trends with respect to a higher incidence of stable disease (odds ratio 1.54 [95% CI 0.77 to 3.11]p=0.12), and reduced incidence of serious adverse events in the treatment group (p=0.074).

Primary Efficacy Analysis	**ITT population (n=333): Xilonix n=222, Placebo= 111**					
	Placebo Responders (n)	Xilonix Responders (n)	Placebo Responders (%)	Xilonix Responders (%)	Relative Increase in Response Rate (%)	p Value
Responders	24	68	22%	31%	42%	0.042

Secondary Analysis	Placebo	Xilonix	Placebo (%)	Xilonix (%)	Relative Change (%)	p Value
Median Change in Platelet Counts (1,000/mm^3)	25	5	na	na	80% (relative magnitude reduction)	0.003
					Relative Improvement in Xilonix arm for Stable Disease (odds ratio)	
Patients with Stable Disease[1]	12	35	12%	17%	54%	0.12
					Relative Risk Reduction (%)	
Number of Serious Adverse Events (SAE)	32	48	29%	22%	25%	0.074

RECIST v1.1. p values are for one-tailed significance testing.

XBiotech to Host Overview of Strategy and Findings for its European Phase III Trial for treatment of Colorectal Cancer with Xilonix™

AUSTIN, TX, January 7, 2016 – XBiotech (NASDAQ: XBIT), the world's leading developer of next-generation True Human™ therapeutic antibodies, announced today it will host a conference call and live audio webcast on Friday, January 8, 2016, at 8:30 a.m. ET, to provide an overview of its strategy and findings for its European Phase III clinical study to evaluate a first-of-a-kind human therapeutic antibody, Xilonix™, in the treatment of advanced colorectal cancer.

Conference Call Information:
Interested participants and investors may access the conference call by dialing:

- 1 (877) 242-7960 (U.S.)
- 1 (330) 863-3267 (international)

An audio webcast will also be accessible via the Investors Relations section of the XBiotech website www.xbiotech.com/about/investors.html. The webcast replay will remain available for 90 days.

About XBiotech
XBiotech is pioneering 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 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 True Human antibodies are cloned directly from individual donors who possess natural immunity against certain diseases. 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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XBiotech Reports Additional Positive Data from Phase III European Trial of Xilonix™ in Advanced Colorectal Cancer

Conference Call and Live Audio Webcast Scheduled for Today at 8:30 a.m. ET

AUSTIN, TX, January 8, 2016 – XBiotech (NASDAQ: XBIT), developer of True Human™ therapeutic antibodies, today announced that it has completed data analysis for its Phase III European study and will hold a conference call to provide additional important information regarding the activity of Xilonix™ in the treatment of advanced, symptomatic colorectal cancer.

In addition to previously announced positive results regarding the primary endpoint of the pivotal study, complete data analysis further demonstrated that key secondary measures of antibody activity were also improved. Inhibition of IL-1 alpha on the surface of platelets may represent an important anti-tumor, disease-modifying activity, due to the mechanism of action of Xilonix. In the study, median platelet counts among placebo patients were found to be increased 5-fold compared to patients who received Xilonix, whose platelet counts remained near baseline levels during the treatment cycle (p=0.003).

Furthermore, while the study was not powered to demonstrate differences in serious adverse events (SAEs) between treatment and placebo groups, there was a 26% reduction in the risk of SAEs in the treatment arm relative to placebo (p=0.062). A treatment-related reduction in SAEs compared to placebo patients is a remarkable and important finding. An SAE is defined as a health-related event that is life-threatening, results in persistent or significant disability, or death. This may be the first report of a placebo controlled, randomized clinical study of an anticancer agent where there was *reduced* incidence of SAEs in a treatment arm. Finally, patients in the treatment arm were found to be 53% more likely to have stable disease compared to placebo at eight weeks (p=0.12).

The trends toward reduced disease progression and a reduction in SAEs is compelling given the small patient population in the study. Together, the Company believes that these secondary findings corroborate the therapeutic value of the antibody in advanced, recalcitrant cancer.

John Simard, CEO of XBiotech, stated, "We believe this study serves as a confirmation that Xilonix is a unique anti-cancer agent for gently treating advanced, even fragile cancer patients. We are also very proud that the study represents a milestone in the development of new clinical endpoints to assess efficacy of novel treatments that help heal patients with advanced disease."

The study included only patients with advanced disease with multiple symptoms that were prognosticators of poor outcome. The study was thus performed on a narrowly defined group of patients living with advanced colorectal cancer. The objective response criteria that constituted the primary endpoint were based on findings of a previous study in advanced cancer patients where antibody therapy was associated with recovery from key disease-related symptoms, including objective findings of increased lean body mass (LBM), and recovery from appetite loss, fatigue and pain. The Company collaborated with the Scientific Advisory Group of the European Medicines Agency (EMA) to use these earlier observations to establish novel objective response criteria to enable evaluation and potential registration of a cancer therapy. Thus the present findings of the Phase III study are believed to provide the first evidence that: (1) new endpoints based on symptom recovery may be used to evaluate an anti-tumor agent in advanced cancer; (2) in patients with advanced cancer, clinical trajectory can be positively altered in the presence of recalcitrant tumor; and (3), Xilonix, a True Human antibody therapeutic, represents a novel treatment for a serious unmet medical need in advanced colorectal cancer.

Conference Call Information:
XBiotech will host a conference call and live audio webcast today at 8:30 a.m. ET to review the strategy and findings from the European Phase 3 Xilonix trial.

Interested participants and investors may access the conference call by dialing:

- 1 (877) 242-7960 (U.S.)
- 1 (330) 863-3267 (International)

An audio webcast will also be accessible via the Investors Relations section of the XBiotech website www.xbiotech.com/about/investors.html. The webcast replay will remain available for 90 days.

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