XBiotech Inc.
Form 10-Q
May 13, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

ý **Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

For the quarterly period ended March 31, 2016

or

¨ **Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

Commission File Number 001-37437

XBIOTECH INC.

(Exact name of registrant as specified in charter)

British Columbia, Canada —	**(IRS Employer**
(State of Incorporation)	**Identification No.)**

8201 E. Riverside Drive, Bldg. 4, Suite 100

Austin, TX 78744

(Address of principal executive offices)(Zip Code)

Telephone Number (512) 386-2900

(Registrant's telephone number, including Area Code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ý No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ý No ¨

1

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See the definitions of “large accelerated filer,” “accelerated filer” and “smaller reporting company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer ¨	Accelerated filer ¨
Non-accelerated filer ý (Do not check if a smaller reporting company)	Smaller reporting company ¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No ý

As of May 13, 2016, there were 32,350,565 shares of the Registrant's common stock issued and outstanding.

2

XBIOTECH INC

THREE MONTHS ENDED MARCH 31, 2016

INDEX

3

CAUTIONARY STATEMENTS REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements, which reflect our current views with respect to, among other things, our operations and financial performance. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q are forward-looking statements. You can identify forward-looking statements by terminology such as “may,” “will,” “should,” “would,” “could,” “expects,” “plans,” “contempla “anticipates,” “believes,” “estimates,” “predicts,” “projects,” “intend” or “continue” or the negative of such terms or other com 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 forward-looking statements include, but are not limited to statements about:

- our ability to obtain regulatory approval to market and sell Xilonix™ in the United States, Europe and elsewhere;
- the initiation, timing, cost, progress and success of our research and development programs, preclinical studies and clinical trials for Xilonix™ and other product candidates;
- our ability to advance product candidates into, and successfully complete, clinical trials;
- our ability to successfully commercialize the sale of Xilonix™ in the United States, Europe and elsewhere;
- our ability to recruit sufficient numbers of patients for our future clinical trials for our pharmaceutical products;
- our ability to achieve profitability;
- our ability to obtain funding for our operations, including research funding;
- our ability to identify additional new products using our True Human™ antibody discovery platform;
- the implementation of our business model and strategic plans;
- our ability to develop and commercialize product candidates for orphan and niche indications independently;
- our commercialization, marketing and manufacturing capabilities and strategy;

- our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others;
- our expectations regarding federal, state and foreign regulatory requirements;
- the therapeutic benefits, effectiveness and safety of our product candidates;
- the accuracy of our estimates of the size and characteristics of the markets that may be addressed by our products and product candidates;
- the rate and degree of market acceptance and clinical utility of Xilonix™ and future products, if any;
- the timing of and our collaborators' ability to obtain and maintain regulatory approvals for our product candidates;
- our expectations regarding market risk, including interest rate changes and foreign currency fluctuations;
- our belief in the sufficiency of our cash flows to meet our needs for at least the next 12 to 24 months;

- our expectations regarding the timing during which we will be an emerging growth company under the JOBS Act;
- our ability to engage and retain the employees required to grow our business;
- our future financial performance and projected expenditures;
- developments relating to our competitors and our industry, including the success of competing therapies that are or become available; and
- estimates of our expenses, future revenue, capital requirements and our needs for additional financing.

All forward looking statements in this Quarterly Report on Form 10-Q involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those under the heading "Risk Factors" included in our annual report for the year ended December 31, 2015 filed with the SEC on March 30, 2016, and elsewhere in this Quarterly Report on Form 10-Q. These factors should not be construed as exhaustive and should be read in conjunction with the other cautionary statements that are included in this Quarterly Report on Form 10-Q. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

This Quarterly Report on Form 10-Q also contains estimates, projections and other information concerning our industry, our business, and the markets for certain medical conditions, including data regarding the estimated size of those markets, and the incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources.

5

XBiotech Inc.

Consolidated Balance Sheets

(in thousands, except share data)

	March 31, 2016 (unaudited)	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$78,225	$91,051
Prepaid expenses and other current assets	1,614	1,990
Total current assets	79,839	93,041
Property and equipment, net	7,715	5,946
Building construction in progress	13,708	10,371
Total assets	$101,262	$109,358
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	$4,846	$4,825
Accrued expenses	1,717	1,466
Total current liabilities	6,563	6,291
Deferred rent	20	17
Total liabilities	6,583	6,308
Shareholders' equity:		
Preferred Stock, no par value, unlimited shares authorized, no shares outstanding	-	-
Common stock, no par value, unlimited shares authorized, 32,292,106 and 32,279,106 shares outstanding at March 31, 2016 and December 31, 2015, respectively	235,751	233,902
Accumulated other comprehensive loss	(164)	(201)
Accumulated deficit	(140,908)	(130,651)
Total shareholders' equity	94,679	103,050
Total liabilities and shareholders' equity	$101,262	$109,358

See accompanying notes.

XBiotech Inc.

Consolidated Statements of Operations

(in thousands, except share and per share data)

	Three Months Ended March 31,	
	2016 (unaudited)	2015 (unaudited)
Operating expenses:		
Research and development	$7,812	$6,784
General and administrative	2,436	1,421
Total operating expenses	10,248	8,205
Loss from operations	(10,248)	(8,205)
Other income (loss):		
Foreign exchange (loss) Gain	(9)	91
Total other income (loss) Gain	(9)	91
Net loss	$(10,257)	$(8,114)
Net loss per share—basic and diluted	$(0.32)	$(0.29)
Shares used to compute basic and diluted net loss per share	32,292,106	27,641,565

See accompanying notes.

XBiotech Inc.

Consolidated Statements of Comprehensive Loss

(in thousands)

	Three Months Ended March 31,	
	2016 (unaudited)	2015 (unaudited)
Net loss	$ (10,257)	$ (8,114)
Foreign currency translation adjustment	38	(98)
Comprehensive loss	$ (10,219)	$ (8,212)

See accompanying notes.

XBiotech Inc.

Consolidated Statements of Cash Flows

(in thousands)

	Three Months Ended March 31,	
	2016 (unaudited)	2015 (unaudited)
Operating activities		
Net loss	$(10,257)	$(8,114)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	179	165
Share-based compensation expense	1,817	1,222
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	408	(82)
Accounts payable	(2,348)	883
Accrued expenses	250	(607)
Deferred rent	4	2
Net cash used in operating activities	(9,947)	(6,531)
Investing activities		
Purchase of property and equipment	(1,543)	(152)
Expenditure on building construction	(1,374)	(419)
Net cash used in investing activities	(2,917)	(571)
Financing activities		
Issuance of common stock and warrants, net	-	2,401
Issuance of common stock under stock option plan	-	8
Collection of subscription receivable	-	410
Deferred offering costs	-	(712)
Net cash provided by financing activities	-	2,107
Effect of foreign exchange rate on cash and cash equivalents	38	(98)
Net change in cash and cash equivalents	(12,826)	(5,093)
Cash and cash equivalents, beginning of period	91,051	57,329
Cash and cash equivalents, end of period	$78,225	$52,236
Supplemental Information:		
Accrued purchases of property and equipment	405,283	404,028
Accrued expenditure on building construction	1,962,917	-

See accompanying notes.

9

XBiotech Inc.

Notes to Consolidated Financial Statements (Unaudited)

1. Organization

XBiotech, Inc. (“XBiotech” or “the Company”) was incorporated in Canada on March 22, 2005. XBiotech USA Inc., a wholly-owned subsidiary of the Company, was incorporated in Delaware, United States (“U.S.”) in November 2007. XBiotech Schweiz AG, a wholly-owned subsidiary of the Company, was incorporated in Zug, Switzerland in August 2010. XBiotech Japan KK, a wholly-owned subsidiary of the Company, was incorporated in Tokyo, Japan in March 2013. XBiotech GmbH, a wholly-owned subsidiary of the Company, was incorporated in Germany in January 2014.

Since its inception, XBiotech has focused on advancing technology to rapidly identify and clone antibodies from individuals that have resistance to disease. At the heart of the Company is a proprietary technical knowhow to translate natural human immunity into therapeutic product candidates.

In 2005, the Company began to develop a new framework for commercial manufacturing, using technology that required less capital, fewer operators and provided greater flexibility than standard industry practices.

With the manufacturing capability to produce its True Human™ antibody therapy, in 2010 the Company began a clinical trial program. The first clinical trial program at MD Anderson Cancer Center began treating the sickest cancer patients irrespective of tumor type. Soon thereafter, the Company used the same antibody therapy in various clinical studies at treatment centers around the U.S. and abroad to investigate the antibody effect in patients that had vascular disease, leukemia, type 2 diabetes, psoriasis or acne.

The Company’s headquarters are located in Austin, Texas.

The Company continues to be subject to a number of risks common to companies in similar stages of development. Principal among these risks are the uncertainties of technological innovations, dependence on key individuals, development of the same or similar technological innovations by the Company’s competitors and protection of proprietary technology. The Company’s ability to fund its planned clinical operations, including completion of its planned trials, is expected to depend on the amount and timing of cash receipts from future collaboration or product sales and/or financing transactions.

2. Significant Accounting Policies

Basis of Presentation

These consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States, or US GAAP.

Basis of Consolidation

These interim unaudited consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP, and Securities and Exchange Commission, or SEC, requirements for interim financial statements. In the Company's opinion, the accompanying unaudited consolidated financial statements have been prepared on the same basis as the audited consolidated financial statements and include all adjustments, consisting of normal, recurring adjustments, necessary for a fair presentation. Certain information and disclosures normally included in the notes to the annual consolidated financial statements prepared in accordance with GAAP have been omitted from these interim unaudited consolidated financial statements pursuant to the rules and regulations of the SEC. Accordingly, these interim unaudited consolidated financial statements should be read in conjunction with the consolidated financial statements and the accompanying notes for the fiscal year ended December 31, 2015, which are included in the Company's Annual Report on Form 10-K, filed with the SEC on March 30, 2016. The results of operations for the three month period ended March 31, 2016 are not necessarily indicative of the results to be expected for the year ending December 31, 2016 or for any other period.

Basis of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All significant intercompany transactions have been eliminated upon consolidation.

Use of Estimates

The preparation of financial statements in accordance with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported values of amounts in the financial statements and accompanying notes. Actual results could differ from those estimates.

Prior to the completion of it initial public offering in April 2015, the Company utilized significant estimates and assumptions in determining the fair value of its common stock. The board of directors determined the estimated fair value of the Company's common stock based on a number of objective and subjective factors, including the prices at which the Company sold shares of its common stock to third parties and external market conditions affecting the biotechnology industry sector.

Research and Development Costs

All research and development costs are charged to expense as incurred. Research and development costs include salaries and personnel-related costs, consulting fees, fees paid for contract research services, the costs of laboratory equipment and facilities, license fees and other external costs. Costs incurred to acquire licenses for intellectual property to be used in research and development activities with no alternative future use are expensed as incurred as research and development.

Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are deferred and capitalized. The capitalized amounts are expensed as the related goods are delivered or the services are performed.

Income Taxes

The Company makes estimates and judgments in determining the need for a provision for income taxes, including the estimation of its taxable income or loss for the each full fiscal year. The Company has accumulated significant

deferred tax assets that reflect the tax effects of net operating loss and tax credit carryovers and temporary difference between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Realization of certain deferred tax assets is dependent upon future earnings. The Company is uncertain about the timing and amount of any future earnings. Accordingly, the Company offsets these deferred tax assets with a valuation allowance. The Company may in the future determine that certain deferred tax assets will likely be realized, in which case the Company will reduce its valuation allowance in the period in which such determination is made. If the valuation allowance is reduced, the Company may recognize a benefit from income taxes in its statement of operations in that period. The Company classifies interest recognized pursuant to its deferred tax assets as interest expense, when appropriate.

Share-Based Compensation

The Company accounts for its share-based compensation awards in accordance with ASC Topic 718, *Compensation-Stock Compensation* (“ASC 718”). ASC 718 requires all share-based payments to employees, including grants of employee stock options, to be recognized in the statements of operations based on their grant date fair values. For stock options granted to employees and to members of the board of directors for their services on the board of directors, the Company estimates the grant date fair value of each option award using the Black-Scholes option-pricing model. The use of the Black-Scholes option-pricing model requires management to make assumptions with respect to the expected term of the option, the expected volatility of the common stock consistent with the expected life of the option, risk-free interest rates and expected dividend yields of the common stock. For awards subject to service-based vesting conditions, the Company recognizes share-based compensation expense, equal to the grant date fair value of stock options on a straight-line basis over the requisite service period.

Share-based compensation expense recognized for the three months ended March 31, 2016 and 2015 was included in the following line items on the Consolidated Statement of Operations (in thousands).

	Three Months Ended March 31,	
	2016	2015
Research and development	$598	$456
General and administrative	1,219	766
Total share-based compensation expense	$1,817	$1,222

The fair value of each option is estimated on the date of grant using the Black-Scholes method with the following assumptions:

	Three Months Ended March 31,	
	2016	2015
Dividend yield	-	-
Expected volatility	65% - 68%	68%
Risk-free interest rate	1.31% - 1.82%	1.39% - 2.12%
Expected life (in years)	5 - 10	5 - 10
Weighted-average grant date fair value per share	$8.01	$9.56

No related tax benefits were recognized for the three months ended March 31, 2016 and 2015.

Cash and Cash Equivalents

The Company considers highly liquid investments with a maturity of three months or less when purchased to be cash equivalents. Cash and cash equivalents consisted primarily of cash on deposit in U.S., German, Swiss and Canadian banks. Cash and cash equivalents are stated at cost which approximates fair value.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to credit risk consist primarily of cash and cash equivalents. The Company holds these investments in highly-rated financial institutions, and limits the amounts of credit exposure to any one financial institution. These amounts at times may exceed federally insured limits. The Company has not experienced any credit losses in such accounts and does not believe it is exposed to any significant

credit risk on these funds. The Company has no off-balance sheet concentrations of credit risk, such as foreign currency exchange contracts, option contracts or other hedging arrangements.

Fair Value Measurements

The Company follows ASC Topic 820, *Fair Value Measurements and Disclosures*, which establishes a fair value hierarchy for those instruments measured at fair value that distinguishes between assumptions based on market date (observable inputs) and the Company's own assumptions (unobservable inputs). The hierarchy consists of three levels:

- Level 1—Unadjusted quoted prices in active markets for identical assets or liabilities.

- Level 2—Quoted prices for similar assets and liabilities in active markets, quoted prices in markets that are not active, or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liability.

- Level 3—Unobservable inputs that reflect the Company's own assumptions about the assumptions market participants would use in pricing the asset or liability in which there is little, if any, market activity for the asset or liability at the measurement date.

At March 31, 2016 and December 31, 2015, the Company did not have any assets or liabilities that are measured at fair value on a recurring basis. The carrying amounts reflected in the balance sheets for cash and cash equivalents, prepaid expenses and other current assets, accounts payable, and accrued expenses approximate their fair values at March 31, 2016 and December 31, 2015, due to their short-term nature.

Property and Equipment

Property and equipment, which consists of land, construction in process, furniture and fixtures, computers and office equipment, scientific equipment, leasehold improvements and vehicles are stated at cost and depreciated over the estimated useful lives of the assets, with the exception of land and construction in process which are not depreciated, using the straight line method. The useful lives are as follows:

- Furniture and fixtures (years) 7
- Office equipment (years) 5
- Leasehold improvements Shorter of asset's useful life or remaining lease term
- Scientific equipment (years) 5
- Vehicles (years) 5

Costs of major additions and betterments are capitalized; maintenance and repairs, which do not improve or extend the life of the respective assets, are charged to expense as incurred. Upon retirement or sale, the cost of the disposed asset and the related accumulated depreciation are removed from the accounts and the resulting gain or loss is recognized.

Building Construction in Progress

Building construction in progress consists of the accumulated expenditures to build the new XBiotech manufacturing facility located in Austin, Texas, which includes the cost for land clearing, architecture design, engineering services, city permits, installation of utilities, construction materials and labor and construction management. Once the building is completed and placed into service, the Company will commence depreciation over its estimated useful life.

Impairment of Long-Lived Assets

The Company periodically evaluates its long-lived assets for potential impairment in accordance with ASC Topic 360, *Property, Plant and Equipment*. Potential impairment is assessed when there is evidence that events or changes in circumstances indicate that the carrying amount of an asset may not be recovered. Recoverability of these assets is assessed based on undiscounted expected future cash flows from the assets, considering a number of factors, including past operating results, budgets and economic projections, market trends and product development cycles. If impairments are identified, assets are written down to their estimated fair value. The Company has not recognized any impairment through March 31, 2016.

Foreign Currency Transactions

Certain transactions are denominated in a currency other than the Company's functional currency of the U.S. dollar, and the Company generates assets and liabilities that are fixed in terms of the amount of foreign currency that will be received or paid. At each balance sheet, the Company adjusts the assets and liabilities to reflect the current exchange rate, resulting in a translation gain or loss. Transaction gains and losses are also realized upon a settlement of a foreign currency transaction in determining net loss for the period in which the transaction is settled.

Comprehensive Income (Loss)

ASC Topic 220, *Comprehensive Income*, requires that all components of comprehensive income (loss), including net income (loss), be reported in the financial statements in the period in which they are recognized. Comprehensive income (loss) is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources, including unrealized gains and losses on investments and foreign currency translation adjustments.

Segment and Geographic Information

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker, or decision making group, in making decisions on how to allocate resources and assess performance. The Company's chief operating decision maker is the Chief Executive Officer. The Company and the chief operating decision maker view the Company's operations and manage its business as one operating segment. Substantially all of the Company's operations are in the U.S. geographic segment.

Net Loss Per Share

Net loss per share ("EPS") is computed by dividing net loss by the weighted average number of common shares outstanding during each period. Diluted EPS is computed by dividing net loss by the weighted average number of common shares and common share equivalents outstanding (if dilutive) during each period. The number of common share equivalents, which include stock options, is computed using the treasury stock method.

Subsequent Events

The Company considered events or transactions occurring after the balance sheet date but prior to the date the consolidated financial statements are available to be issued for potential recognition or disclosure in its consolidated financial statements. The Company has evaluated subsequent events through the date the consolidated financial statements were available for issuance for potential recognition or disclosure in its consolidated financial statements.

Recent Accounting Pronouncements

In August 2014 the FASB issued ASU 2014-15*, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*. The ASU is intended to define management's responsibility to evaluate whether there is substantial doubt about an organization's ability to continue as a going concern and to provide related footnote disclosures. For all entities, the ASU is effective for annual periods ending after December 15, 2016 and interim periods within annual periods beginning after December 15, 2016.

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842). The core change with ASU 2016-2 is the requirement for the recognition of lease assets and lease liabilities by lessees for those leases classified as operating leases under previous GAAP. The new standard is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018, with early adoption permitted. The Company is currently evaluating the effect that the adoption of ASU 2016-02 will have on its financial statements.

In March 2016, the FASB issued ASU No. 2016-09, "Improvements to Employee Share-Based Payment Accounting," or ASU 2016-09, which amends ASC Topic 718, "Compensation – Stock Compensation." ASU 2016-09 simplifies several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. The standard is effective for fiscal years beginning after December 31, 2016, and interim periods within those years and early adoption is permitted. The Company is currently evaluating how the adoption of this standard will impact its consolidated f