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 ¨

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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.

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XBIOTECH INC

THREE MONTHS ENDED MARCH 31, 2016

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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.

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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.

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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 financial statements.

3. Income Taxes

The Company did not provide for income taxes in 2016 because the Company has projected net loss for all jurisdictions for the full year 2016. The Company has recorded a full valuation allowance for its net deferred tax assets in 2016 and 2015.

4. Common Stock

Pursuant to its Articles, the Company has an unlimited number of shares available for issuance with no par value.

From January to March 2015, warrants to purchase a total of 164,999 shares of common stock were exercised at $15.00 per share for a total of $2.5 million in proceeds. Also, the Company received approximately $8,000 in January 2015 from 15,000 exercised stock options at $0.55 per share.

On April 17, 2015, the Company sold 4.0 million shares of common stock at $19.00 per share in its Initial Public Offering (“IPO”) resulting in net proceeds of $70.6 million.

From April to June 2015, excluding the IPO, the Company issues 208,333 shares of common stock for total proceeds of approximately $3.1 million from the exercise of warrants by common stock shareholders. Also, the Company received $0.7 million from 106,000 exercised stock options.

In July 2015, 12,000 stock options were exercised at a price of $2.50 for total proceeds of $30,000.

From October through December 31, 2015, 226,141 shares of common stock were issued upon the exercise of stock option at the price $ 0.53 to $10 per share for a total of $639,253.

In January 2016, 13,000 stock options were exercised at a price of $2.50 for total proceeds of $32,500 on January 28th. The Company hasn’t received the proceeds by March 31, 2016.

5. Common Stock Options

On November 11, 2005, the board of directors of the Company adopted a stock option plan (“the Plan”) pursuant to which the Company may grant incentive stock options to directors, officers, employees or consultants of the Company or an affiliate or other persons as the Compensation Committee may approve.

All options will be non-transferable and may be exercised only by the participant, or in the event of the death of the participant, a legal representative until the earlier of the options’ expiry date or the first anniversary of the participant’s death, or such other date as may be specified by the Compensation Committee.

The term of the options is at the discretion of the Compensation Committee, but may not exceed 10 years from the grant date. The options expire on the earlier of the expiration date or the date three months following the day on which the participant ceases to be a director, officer or employee of or consultant to the Company, or in the event of the termination of the participant with cause, the date of such termination.

The number of common shares reserved for issuance to any one person pursuant to this Plan shall not, in aggregate, exceed 5% of the total number of outstanding common shares. The exercise price per common share under each option will be the fair market value of such shares at the time of the grant. Upon stock option exercise, the Company issues new shares of common stock.

A summary of changes in common stock options issued under the Plan is as follows:

	Options	Exercise Price	Weighted-Average Exercise Price
Options outstanding at December 31, 2015	4,786,577	$0.53 - $21.99	$ 8.02
Granted	357,833	7.71 - 9.45	8.01
Exercised	(13,000)	2.50	2.50
Forfeitures	(48,250)	0.55 - 16.91	11.50
Options outstanding at March 31, 2016	5,083,160	$0.55 - $21.99	$ 8.00

As of March 31, 2016, there was approximately $4.6 million of unrecognized compensation cost, related to stock options granted under the Plan which will be amortized to stock compensation expense over the next 2.16 years.

6. Net Loss Per Share

The following summarizes the computation of basic and diluted net loss per share for the three months ended March 31, 2016 and 2015 (in thousands, except share and per share data):

	Three Months Ended March 31,	
	2016	2015
Net loss	$(10,257)	$(8,114)
Weighted-average number of common shares—basic and diluted	32,292,106	27,641,565
Net loss per share—basic and diluted	$(0.32)	$(0.29)

The following potentially dilutive securities outstanding, prior to the use of the treasury stock method or if-converted method, have been excluded from the computation of diluted weighted-average common shares outstanding, because including them would have had an anti-dilutive effect due to the losses reported.

	Three Month Ended March 31,	
	2016	2015
Stock options	5,083,160	4,838,540
Warrants to purchase common stock	-	208,333
Total	5,083,160	5,046,873

7. Related-Party Transactions

Legal fees of approximately $22,000 were incurred to a law firm for legal services rendered in which a former director of the Company is a senior partner in the three months ended March 31, 2015. The Company had outstanding accounts payable to the same firm in the amount of approximately $12,000 as at March 31, 2015. No related-party transaction incurred in the three months ended March 31, 2016.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Overview

XBiotech is a clinical-stage biopharmaceutical company engaged in discovering and developing True Human™ monoclonal antibodies for treating a variety of different diseases. True Human™ monoclonal antibodies are those which occur naturally in human beings—as opposed to being derived from animal immunization technologies or otherwise engineered. We believe that naturally occurring monoclonal antibodies have the potential to be safer and more effective than their non-naturally occurring counterparts. While primarily focused on bringing our lead product candidate to market, we have also developed a proprietary True Human™ monoclonal antibody discovery platform and manufacturing system.

We have never been profitable and, as of March 31, 2016, we had an accumulated deficit of $140.9 million. We had net losses of $10.3 and $8.1 million for three months ended March 31, 2016 and 2015, respectively. We expect to incur significant and increasing operating losses for the foreseeable future as we advance our drug candidates from discovery through preclinical testing and clinical trials and seek regulatory approval and eventual commercialization. In addition to these increasing research and development expenses, we expect general and administrative costs to increase as we add personnel and begin to operate as a public company. We will need to generate significant revenues to achieve profitability, and we may never do so. As of March 31, 2016, we had 83 employees.

Recent Events:

Clinical trial and construction of the new manufacturing facility Highlights

As of March 2016, XBiotech has achieved significant milestones with it's Xilonix™ and 514G3 programs. Enrollment on a Phase III Symptomatic Colorectal Cancer Study has been completed, with enrollment of 335 subjects. Because the study endpoints were satisfactorily met, XBiotech decided to proceed with the submission of a Marketing Authorization Application to the European Medicines Agency, and possibly other foreign regulatory authorities. Additionally, the Staphylococcus Aureus Bacteremia Phase I and II Study with a brand new antibody therapy, 514G3, has completed enrollment for Phase I. Phase II commenced once it was established that there were no dose-related toxicities in Phase I.

There was significant progress in the Q1 2016 with regard to construction of the new manufacturing facility located in Austin Texas. During the Quarter the build out of the interior administrative and lab spaces continued. Installation of HVAC equipment and duct work, ceiling and wall panels as part of the clean room construction activities also progressed. Construction of utility systems to support manufacturing, including electrical, the purified water system, and gas distribution systems began in Q1 and is progressing on schedule. While construction has moved forward significantly, additional delays due to long lead time equipment procurement have been incurred. XBiotech now anticipates final building completion in the August 2016 time frame with plant shakedown and validation starting immediately thereafter. We should begin producing antibody to support registration of the new facility late in Q3 2016.

Revenues

To date, we have not generated any revenue. Our ability to generate revenue and become profitable depends on our ability to successfully commercialize our lead product candidate, Xilonix™, or any other product candidate we may advance in the future.

Research and Development Expenses

Research and development expense consists of expenses incurred in connection with identifying and developing our drug candidates. These expenses consist primarily of salaries and related expenses, stock-based compensation, the purchase of equipment, laboratory and manufacturing supplies, facility costs, costs for preclinical and clinical research, development of quality control systems, quality assurance programs and manufacturing processes. We charge all research and development expenses to operations as incurred.

Clinical development timelines, likelihood of success and total costs vary widely. We do not currently track our internal research and development costs or our personnel and related costs on an individual drug candidate basis. We use our research and development resources, including employees and our drug discovery technology, across multiple drug development programs. As a result, we cannot state precisely the costs incurred for each of our research and development programs or our clinical and preclinical drug candidates. From inception through March 31, 2016, we have recorded total research and development expenses, including share-based compensation, of $108.9 million. Our total research and development expenses for the three months ended March 31, 2016 and 2015 were $7.8 million and $6.8 million, respectively. Share-based compensation accounted for $0.6 million and $0.5 million for the three months ended March 31, 2016 and 2015, respectively.

Research and development expenses, as a percentage of total operating expenses for the three months ended March 31, 2016 and 2015 were 76% and 83%, respectively. The percentages, *excluding* stock-based compensation, for the three months ended March 31, 2016 and 2015, were 86% and 91%, respectively.

As planned, our clinical costs have increased as we advanced Xilonix™ as an anti-cancer therapy for treating last-line metastatic colorectal cancer, under a regulatory pathway through Phase III clinical trials in the US, Europe, Australia and Israel. We will further expand the studies to South America and Canada, with all territories expected to be active during Q2 2016. Our clinical study underway in Europe, that is regulated by the European Medicines Agency (EMA), completed enrollment in November, 2015. The submission for marketing approval to the EMA was completed in March 2016 which could position the Company to generate related revenues in 2017 if it receives EMA marketing approval and the Company successfully completes its commercialization plan for Xilonix™.

The clinical research and development costs will also increase as we have launched a Phase I and II clinical study of novel True Human™ therapeutic antibody for treating serious infections due to *Staphylococcus aureus* in the U.S. We expect to complete expansion of this study into Europe, South Korea and Taiwan for participation in the Phase II portion by the end of Q3 2016.

The Company’s plans to pursue an advanced regulatory path for Pyoderma Gangrenosum is on hold indefinitely while we await the outcome of other programs in later stages of development. In the meantime, based on the results of our preclinical studies, we anticipate that we will select drug candidates and research projects for further development on an ongoing basis in response to their preclinical and clinical success as well as commercial potential. For R&D

candidates in early stages of development, it is premature to estimate when material net cash inflows from these projects might occur.

Due to the fact that our drug candidates are in the early stage of development, we cannot estimate anticipated completion dates and when we might receive material net cash inflows from our research and development projects.

General and Administrative Expenses

General and administrative expense consists primarily of salaries and related expenses for personnel in administrative, finance, business development and human resource functions, as well as the legal costs of pursuing patent protection of our intellectual property and patent filing and maintenance expenses, stock–based compensation, and professional fees for legal services. Our total general and administration expenses for the three months ended March 31, 2016 and 2015 were $2.4 million and $1.4 million, respectively. Share-based compensation accounted for $1.2 million and $0.8 million for the three months ended March 31, 2016 and 2015, respectively.

Critical Accounting Policies

Our Management's Discussion and Analysis of our Financial Condition and Results of Operations is based on our financial statements, which have been prepared in conformity with generally accepted accounting principles in the United States, or US GAAP. The preparation of our financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and expenses incurred during the reported periods.

We base estimates on our historical experience, known trends and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in the notes to our financial statements appearing in this prospectus, we believe that the following accounting policies are the most critical to understanding and evaluating our reported financial results.

Stock-Based Compensation

Stock-based awards are measured at fair value at each grant date. We recognize stock-based compensation expenses ratably over the requisite service period of the option award.

Determination of the Fair Value of Stock-Based Compensation Grants

The determination of the fair value of stock-based compensation arrangements is affected by a number of variables, including estimates of the fair value of our common stock, expected stock price volatility, risk-free interest rate and the expected life of the award. We value stock options using the Black-Scholes option-pricing model, which was developed for use in estimating the fair value of traded options that are fully transferable and have no vesting restrictions. Black-Scholes and other option valuation models require the input of highly subjective assumptions, including the expected stock price volatility. If we made different assumptions, our stock-based compensation expenses, net loss, and net loss per common share could be significantly different. Prior to our IPO in April 2015, we issued common stock for cash consideration to new investors. We believe that such transactions represent the best evidence of fair value of our common stock. Therefore, we used the sales price of our common stock during the three months ended March 31,2015 as the fair value of our common stock.

The following summarizes the assumptions used for estimating the fair value of stock options granted during the periods indicated:

	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		

We have assumed no dividend yield because we do not expect to pay dividends in the foreseeable future, which is consistent with our past practice. The risk-free interest rate assumption is based on observed interest rates for U.S. Treasury securities with maturities consistent with the expected life of our stock options. The expected life represents the period of time the stock options are expected to be outstanding and is based on the simplified method when the stock option includes “plain vanilla” terms. Under the simplified method, the expected life of an option is presumed to be the midpoint between the vesting date and the end of the agreement term. We used the simplified method due to the lack of sufficient historical exercise data to provide a reasonable basis upon which to otherwise estimate the expected life of the stock options. For stock options that did not include “plain vanilla” terms we used the contractual life of the stock option as the expected life. Such stock options consisted primarily of options issued to our board of directors that were immediately vested at issuance. Expected volatility is based on historical volatilities for publicly traded stock of comparable companies over the estimated expected life of the stock options.

We based our estimate of pre-vesting forfeitures, or forfeiture rate, on historical forfeiture rates. We apply the estimated forfeiture rate to the total estimated fair value of the awards, as derived from the Black-Scholes model, to compute the stock-based compensation expenses, net of pre-vesting forfeitures, to be recognized in our consolidated statements of operations.

Results of Operations

Revenue

We did not record any revenue during the three months ended March 31, 2016 and 2015.

Expenses

Research and Development

Research and Development costs are summarized as follows (in thousands):

	Three Months Ended March 31,		Increase (Decrease)	% Increase (Decrease)
	2016	2015		
Salaries and related expenses	$1,858	$1,430	$ 428	30 %
Laboratory and manufacturing supplies	776	1,335	(559)	(42 %)
Clinical trials and sponsored research	3,656	2,689	967	36 %
Stock-based compensation	597	456	141	31 %
Other	925	874	51	6 %
Total	$7,812	$6,784	$ 1,028	15 %

We do not currently track our internal research and development costs or our personnel and related costs on an individual drug candidate basis. We use our research and development resources, including employees and our drug discovery technology, across multiple drug development programs. As a result, we cannot state precisely the costs incurred for each of our research and development programs or our clinical and preclinical drug candidates.

Research and development expenses increased by $10.0 million to $7.8 million for the three months ended March 31, 2016, compared to $6.8 million for the three months ended March 31, 2015. This increase was principally due to a $10.0 million increase in clinical trial activities mainly in Europe and the US. Labor costs also increased due to the increase of current employee's salaries and increase in the size of the workforce from 39 to 75.

General and Administrative

General and administrative costs are summarized as follows (in thousands):

	Three Months Ended March 31,		Increase	% Increase
	2016	2015	(Decrease)	(Decrease)
Salaries and related expenses	$ 527	$ 199	$ 328	165 %
Patent filing expense	146	227	(81)	(36 %)
Stock-based compensation	1,219	767	452	59 %
Professional fees	92	132	(40)	(30 %)
Other	452	96	356	371 %
Total	$ 2,436	$ 1,421	$ 1,015	71 %

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General and administrative expense increased by $1.0 million to $2.4 million for the three months ended March 31, 2016, compared to $1.4 million for the three months ended March 31, 2015. The increase was primarily related to increase in stock–based compensation expenses of $0.5 million, due to the grant of stock options to board members in 2016 that were immediately vested. The increase is also due to higher salaries and related expenses in 2016 because of the growing size of our workforce and a $135,100 bonus payment to an executive officer in March 2016.

Other income

The following table summarizes other income (in thousands):

	Three Months Ended March 31,	
	2016	2015
Foreign exchange gain	$(9)	$91
Total	$(9)	$91

Other income consists primarily of a $9 thousand loss for the three months ended March 31, 2016 compared to a $91 thousand gain for the three months ended March 31, 2015.

Liquidity and Capital Resources

Our cash requirements could change materially as a result of the progress of our research and development and clinical programs, licensing activities, acquisitions, divestitures or other corporate developments.

Since our inception on March 22, 2005 through March 31, 2016, we have funded our operations principally through the private placement of equity securities, which have provided aggregate cash proceeds of approximately $221.0 million. The following table summarizes our sources and uses of cash (in thousands):

	Three Months Ended March 31,	
Net cash (used in) provided by:	2016	2015
Operating activities	$(9,947)	$(6,531)
Investing activities	(2,917)	(571)
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)

During the three months ended March 31, 2016 and 2015, our operating activities used net cash of $9.9 million and $6.5 million, respectively. The use of net cash in each of these periods primarily resulted from our net losses. The increase in net loss from operations for the three months ended March 31, 2016 as compared to the three months ended March 31, 2015 was due to increases in clinical trial activities in Europe and the US and the labor cost.

During the three months ended March 31, 2016 and 2015, our investing activities used net cash of $2.9 million and $0.6 million, respectively. We spent approximately $2.6 million more on the construction of new facilities during the three months ended March 31, 2016 compared to the three months ended March 31, 2015.

During the three months ended March 31, 2015, our financing activities provided net cash proceeds of $2.1 million and no cash provided in the three months ended March 31, 2016. During the three months ended March 31, 2015, we received requests from investors for the exercise of warrants to purchase a total of 164,999 shares of common stock at $15.00 per share for a total of approximately $2.4 million in net proceeds, and we also incurred deferred offering costs of $712 thousand, which consist of direct incremental legal, accounting and other professional service fees related to our IPO. In January 2015, we received the previously outstanding subscription receivable in the amount of $410 thousand.

We expect to continue to incur substantial operating losses in the future. We will not receive any product revenue until a drug candidate has been approved by the FDA or similar regulatory agencies in other countries and successfully commercialized. As of March 31, 2016, our principal sources of liquidity were our cash and cash equivalents, which totaled approximately $78.2 million.

Contractual Obligations and Commitments

On January 12, 2008, we entered a lease agreement to lease our facility in Austin, Texas. On September 15, 2010, we entered into a second lease agreement to lease additional space in Austin, Texas. On March 20, 2014, we extended the lease for an additional 21 months on the same terms and rental rates as the current lease. Rent expense was $179 thousand and $105 thousand for the three months ended March 31, 2016 and 2015, respectively. On February 28, 2015, we extended the lease for another 4 years. The future minimum lease payments are as follows as of March 31, 2016 (in thousands):

Contractual Obligations	Total	Less than 1 Year	1 - 3 Years	More than 3 years
Operating facility leases	$1,348	$ 452	$ 896	$ —
Total contractual obligations	$1,348	$ 452	$ 896	$ —

Off-Balance Sheet Arrangements

Since inception, we have not engaged in any off-balance sheet activities, including the use of structured finance, special purpose entities or variable interest entities.

Item 3. Quantitative and Qualitative Disclosure of Market Risks

The Company is not currently exposed to material market risk arising from financial instruments, changes in interest rates or commodity prices, or fluctuations in foreign currencies. The Company has no need to hedge against any of the foregoing risks and therefore currently engages in no hedging activities.

Item 4. Controls and Procedures

Management's Evaluation of our Disclosure Controls and Procedures

As of the end of the period covered by this Quarterly Report on Form 10-Q, an evaluation was carried out by the Company’s management, with the participation of the Chief Executive Officer and Principal Financial Officer, of the effectiveness of the Company’s disclosure controls and procedures, as defined in Rule 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934. Based on such evaluation, the Chief Executive Officer and Principal Financial Officer concluded that the Company’s disclosure controls and procedures are effective to ensure that information required to be disclosed in the reports the Company files or furnishes under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and regulations, and are operating in an effective manner.

Changes in Internal Control Over Financial Reporting

There was no change in our internal control over financial reporting that occurred during the first quarter of the year ended December 31, 2016 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Limitations on Effectiveness of Controls and Procedures

In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

On December 1, 2015, a purported securities class action complaint captioned *Yogina Rezko v. XBiotech Inc., John Simard, Queena Han and WR Hambrecht & Co., LLC* was filed against us, certain of our officers and directors and the underwriter for our initial public offering in the Superior Court for the State of California, Los Angeles County. On December 2, 2015, a purported securities class action complaint captioned *Linh Tran v. XBiotech Inc., John Simard and Queena Han* was filed against us and certain of our officers and directors in U.S. District Court for the Western District of Texas. The lawsuits are based on substantially similar factual allegations and purport to be class actions brought on behalf of purchasers of the Company's securities during the period from April 15, 2015 through November 23, 2015. The complaint filed in California state court alleges that the defendants violated the Securities Act of 1933, as amended (the "Securities Act"), and the complaint filed in federal court alleges that the defendants violated the Securities Exchange Act of 1934, as amended (the "Exchange Act"), in each case by making materially false and misleading statements concerning the Company's Phase III clinical trial conducted in Europe to assess Xilonix™ as a treatment for colorectal cancer. The California complaint purports to assert claims for violations of Sections 11, 12(a)(2) and 15 of the Securities Act, and the federal complaint purports to assert claims for violation of Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder. Both complaints seek, on behalf of the purported class, an unspecified amount of monetary damages, interest, fees and expenses of attorneys and experts, and other relief.

Both the federal case and the California case are in the early procedural stages. On February 24th, 2016, following a proceeding to select a lead plaintiff in the federal case, the court issued an order appointing Mr. Kresimir Corak as lead plaintiff. The plaintiff filed an amended complaint in the federal case on April 8th, 2016. In the California case, we expect the plaintiffs to file an amended complaint in May 2016, and we anticipate making certain procedural motions also in May 2016. No trial or other dates have been set.

Item 1A. Risk Factors

There have been no material changes to the risk factors included in our Annual Report on Form 10-K for the year ended December 31, 2015. Please carefully consider the information set forth in this Quarterly Report on Form 10-Q and the risk factors discussed in Part I, "Item 1A. Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2015, which could materially affect our business, financial condition or future results. The risks described in our Annual Report on Form 10-K, as well as other risks and uncertainties, could materially and adversely affect our business, results of operations and financial condition, which in turn could materially and adversely affect the trading price of shares of our Common Stock. Additional risks not currently known or currently material to us may also harm our business.

Item 2. Unregistered Sale of Equity Securities and Use of Proceeds

Not Applicable.

Item 3. Defaults upon Senior Securities

Not Applicable.

Item 4. Mine Safety Disclosures

Not Applicable.

Item 5. Other Information.

Not Applicable.

Item 6. Exhibits.

31.1	Certification of Principal Executive Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.
31.2	Certification of Principal Financial Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.
32.1	Certification of Principal Executive Officer and Principal Financial Officer Required Under Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. §1350.
101	The following financial statements from the XBiotech Inc. Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, formatted in Extensive Business Reporting Language (XBRL): (i) condensed consolidated balance sheets, (ii) condensed consolidated statements of operations, (iii) condensed consolidated statements of comprehensive loss, (iv) condensed consolidated statements of cash flows and (v) notes to condensed consolidated financial statements (detail tagged).

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, thereunto duly authorized.

Date: May 13, 2016

XBIOTECH INC.

By: /S/ John Simard
John Simard
President, Chief Executive Officer and Director (*Principal Executive Officer*)

Date: May 13, 2016

By: /S/ Queena Han

Queena Han
Vice President, Finance and Human Resources, and Secretary (*Principal Financial Officer and Principal Accounting Officer*)

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