

XBiotech Inc.
Form 10-Q
November 13, 2015

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 September 30, 2015**

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)

Canada

(State or other jurisdiction of incorporation or organization)

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)

N/A

(IRS Employer

Identification Number.)

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

Yes 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 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 (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

As of November 10, 2015, the registrant had 32,184,465 shares of common stock outstanding.

XBIOTECH INC.

THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2015

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XBiotech Inc.

Consolidated Balance Sheets

(in thousands, except share data)

	September 30, 2015 (unaudited)	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	\$ 105,680	\$57,329
Prepaid expenses and other current assets	1,907	411
Deferred offering costs	—	324
Total current assets	107,587	58,064
Property and equipment, net	4,854	3,227
Building construction in progress	6,606	886
Total assets	\$ 119,047	\$62,177
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	\$ 3,964	\$1,629
Accrued expenses	994	1,518
Total current liabilities	4,958	3,147
Long-term liabilities:		
Deferred rent	12	—
Total liabilities	4,970	3,147
Shareholders' equity:		
Common stock, no par value, unlimited shares authorized, 32,052,965 and 27,546,632 shares outstanding at September 30, 2015 and December 31, 2014, respectively	232,850	152,351
Accumulated other comprehensive loss	(11)	(153)
Accumulated deficit	(118,762)	(93,168)
Total shareholders' equity	114,077	59,030
Total liabilities and shareholders' equity	\$ 119,047	\$62,177
<i>See accompanying notes.</i>		

XBiotech Inc.

Consolidated Statements of Operations

(in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
	(unaudited)	(unaudited)	(unaudited)	(unaudited)
Operating expenses:				
Research and development	\$9,731	\$4,341	\$20,897	\$9,937
General and administrative	1,083	2,639	4,542	5,452
Total operating expenses	10,814	6,980	25,439	15,389
Loss from operations	(10,814)	(6,980)	(25,439)	(15,389)
Other income (loss):				
Foreign exchange income (loss)	78	17	(155)	17
Total other income (loss)	78	17	(155)	17
Net loss	\$(10,736)	\$(6,963)	\$(25,594)	\$(15,372)
Net loss per share—basic and diluted	\$(0.33)	\$(0.29)	\$(0.84)	\$(0.64)
Shares used to compute basic and diluted net loss per share	32,050,565	24,116,917	30,342,741	23,873,486
<i>See accompanying notes.</i>				

XBiotech Inc.

Consolidated Statements of Comprehensive Loss

(in thousands)

	Three Months Ended September 30, 2015		Nine Months Ended September 30, 2015	
	2014	(unaudited)	2014	(unaudited)
Net loss	\$(10,736)	\$ (6,963)	\$(25,594)	\$ (15,372)
Foreign currency translation adjustment	(77)	100	142	(4)
Comprehensive loss	\$(10,813)	\$ (6,863)	\$(25,452)	\$ (15,376)

See accompanying notes.

XBiotech Inc.

Consolidated Statements of Cash Flows

(in thousands)

	Nine Months Ended September 30,	
	2015	2014
	(unaudited)	(unaudited)
Operating activities		
Net loss	\$ (25,594)	\$ (15,372)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	510	433
Share-based compensation expense	3,355	4,972
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(1,496)	75
Accounts payable	1,124	717
Accrued expenses	(524)	926
Deferred rent	12	—
Net cash used in operating activities	(22,613)	(8,249)
Investing activities		
Purchase of property and equipment	(1,959)	(818)
Expenditures on building construction	(4,687)	(28)
Net cash used in investing activities	(6,646)	(846)
Financing activities		
Net proceeds from Initial Public Offering	70,558	—
Issuance of common stock and warrants, net	5,497	17,351
Issuance of common stock under stock option plan	678	—
Collection of stock subscription receivable	410	—
Deferred offering costs	325	—
Net cash provided by financing activities	77,468	17,351
Effect of foreign exchange rate on cash and cash equivalents	142	(4)
Net change in cash and cash equivalents	48,351	8,252
Cash and cash equivalents, beginning of period	57,329	7,244
Cash and cash equivalents, end of period	\$ 105,680	\$ 15,496
<i>See accompanying notes.</i>		

XBiotech Inc.

Notes to Consolidated Financial Statements

1. 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.

In the Company's opinion, the accompanying interim 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 fiscal year ended December 31, 2014, which are included in the Company's Registration Statement on Form S-1, filed with the SEC on April 14, 2015. The results of operations for the three and nine months ended September 30, 2015, are not necessarily indicative of the results to be expected for the year ending December 31, 2015, 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 its initial public offering on April 15, 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 clinical trial research services, the costs of laboratory consumables, 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 costs.

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 full fiscal year. The Company has accumulated significant deferred tax assets that reflect the tax effects of net operating losses and tax credit carryovers and temporary differences 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.

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 life of the option and 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 and nine months ended September 30, 2015 and 2014 was included in the following line items on the Consolidated Statements of Operations (in thousands).

	Three Months Ended September 30, 2015		Nine Months Ended September 30 2014	
Research and development	\$701	\$2,269	\$1,677	\$2,810
General and administrative	185	255	1,678	2,162
Total share-based compensation expense	\$886	\$2,524	\$3,355	\$4,972

No related tax benefits were recognized for the three months and nine months ended September 30, 2015 and 2014.

Cash and Cash Equivalents

The Company considers highly liquid investments with a maturity of 90 days 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 data (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 September 30, 2015 and December 31, 2014, the Company did not have any assets or liabilities that were remeasured 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 September 30, 2015 and December 31, 2014, due to their short-term nature.

Property and Equipment

Property and equipment, which consists of land, 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 which is 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 cleaning, architecture design, engineering services, city permits, installation of utilities, construction materials and labor and construction management.

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 September 30, 2015.

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 date, 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. We have evaluated subsequent events through the date of filing this Form 10-Q.

Recent Accounting Pronouncements

In June 2014 the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update 2014-10, *Elimination of Certain Financial Reporting Requirements, including an Amendment to Variable Interest Entities Guidance in Topic 810 Consolidation*. These updates remove the definition of a development stage entity from the Master Glossary of the ASC, thereby removing the financial reporting distinction between development stage entities and other reporting entities from U.S. GAAP. In addition, the amendments eliminate the requirements for development stage entities to (1) present inception-to-date information in the statements of income, cash flows, and shareholder equity, (2) label the financial statements as those of a development stage entity, (3) disclose a description of the development stage activities in which the entity is engaged, and (4) disclose in the first year in which the entity is no longer a development stage entity that in prior years it had been in the development stage. This standard is effective for annual reporting periods beginning after December 15, 2014. The Company has early adopted this

standard in the presentation of its financial statements.

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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.

2. Income Taxes

The Company did not provide for income taxes in 2015 because the Company has projected net loss for all jurisdictions for the full year 2015. The Company has recorded a full valuation allowance for its net deferred tax assets in 2015 and 2014.

3. Common Stock

In February 2014, the Company sold 1.2 million shares of common stock for total proceeds of approximately \$12.0 million from the exercise of warrants by its warrant holders. From July through November 18, 2014, the Company sold approximately 601,000 shares of common stock at a price of \$15.00 per share for total proceeds of approximately \$9.0 million. Each share had one warrant attached, which would be exercisable for 180 days into a single common share in the Company at a price of \$15.00 per share. As of December 31, 2014, the Company had total warrants outstanding for the purchase of 493,000 shares of common stock at a price of \$15.00 per share.

From November 24, 2014 through December 31, 2014, the Company sold 3.0 million shares of common stock at \$15.00 per share pursuant to stock subscription agreements for total proceeds of \$44.8 million of which \$410,000 remained uncollected as of December 31, 2014 and was received in January 2015. The Company incurred issuance costs of approximately \$1.9 million in cash and \$0.4 million in non-cash consideration.

In December 2014, 15,000 stock options were exercised at a price of \$10.00 for total proceeds of \$0.15 million.

From January to March 2015, the Company 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 \$2.4 million. Also, the Company received approximately \$8,000 in January 2015 from 15,000 exercised 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 sold 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.

4. 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 and non-qualified stock options to directors, officers, employees or

consultants of the Company or an affiliate or other persons as the Compensation Committee may approve.

On March 13, 2015, the shareholders approved the 2015 Equity Incentive Plan adopted by the board of directors which approves the granting of incentive stock options, non-qualified stock options, restricted stock units, performance stock units and share appreciation rights to directors, officers, employees and consultants. The Company may grant incentive stock option and other stock-based awards to officers and employees as defined in Section 422 of the Internal Revenue Code of 1986 and may grant stock options and other stock based-awards to directors and consultants of the Company.

In February and August 2011 the Company granted stock options to a non-employee consultant that vest over 3 and 4 years, respectively. The fair value of these awards is remeasured at each reporting date until the date the consultant's services are completed.

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, 2014	4,884,165	\$0.55– \$15.00	\$ 7.03
Granted	65,000	15.00	15.00
Exercised	(15,000)	0.56	0.56
Forfeitures	(95,625)	0.55 – 15.00	8.83
Options outstanding at March 31, 2015	4,838,540	\$0.55– \$15.00	\$ 7.12
Granted	219,528	10.00– 21.99	19.04
Exercised	(106,000)	2.50 – 10.00	6.32
Options outstanding at June 30, 2015	4,952,068	0.57 – 21.99	7.66
Granted	65,900	\$16.91	\$ 16.91
Exercised	(12,000)	2.50	2.50
Forfeitures	(7,625)	10.00– 15.00	14.26
Options outstanding at September 30, 2015	4,998,343	0.57 – 21.99	7.77

As of September 30, 2015, there was approximately \$6.0 million of unrecognized compensation cost, related to stock options granted under the Plan which will be amortized to stock compensation expense over the next 2.11 years.

5. Net Loss per Share

The following summarizes the computation of basic and diluted net loss per share for the three months and nine months ended September 30, 2015 and 2014 (in thousands, except share and per share data):

	Three Months Ended		Nine Months Ended	
	September 30, 2015	2014	September 30, 2015	2014
Net loss	\$(10,736)	\$(6,963)	\$(25,594)	\$(15,372)
Weighted-average number of common shares—basic and diluted	32,050,565	24,116,917	30,342,741	23,873,486
Net loss per share—basic and diluted	\$(0.33)	\$(0.29)	\$(0.84)	\$(0.64)

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.

	Nine Months Ended	
	September 30, 2015	2014
Stock options	4,998,343	4,480,665
Warrants to purchase common stock	—	—
Total	4,998,343	4,480,665

6. Subsequent Events

Subsequent to September 30, 2015, the Company received requests from employees for the exercise of stock options to purchase 13,1500 shares of the Company's common stock for a total of \$359,876.92.

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

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,” “contemplates,” “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

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 in this Quarterly Report on Form 10-Q, include, among other things, those under the heading “Risk Factors” included in our Prospectus filed with the Securities and Exchange Commission (“SEC”) on April 16th, 2015, 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. 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.

Overview

XBiotech Inc. 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, Xilonix™, 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 September 30, 2015, we had an accumulated deficit of \$118.8 million. We had net losses of \$10.8 million and \$25.6 million for three months and nine months ended September 30, 2015, respectively, compared to \$7.0 million and \$15.4 million for three months and nine months ended September 30, 2014, 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. On April 17, 2015, the Company closed its initial public offering of 4,000,000 shares of its common stock at a price of \$19.00 per share for a total offering amount of \$76,000,000, before underwriting discounts, commissions and other Company expenses. Net proceeds to the Company totaled approximately \$70.6 million after deducting underwriting discounts and commissions of \$3.8 million and other offering expenses of approximately \$1.6 million. As of September 30, 2015, we had 73 employees.

Recent Events:

Clinical trial and construction of the new manufacturing facility Highlights

As of September 30, 2015 XBiotech has achieved some significant milestones with its Xilonix and 514G3 programs. Enrollment on a Phase III Symptomatic Colorectal Cancer Study has been completed and 61 subjects have been randomized and dosed. Additionally, the first dose cohort has been enrolled on a Staphylococcus Aureus Bacteremia Phase I/II Study with a brand new antibody therapy, 514G3. Having met this milestone, sites were given the green light to advance to the next dose level in the Phase I portion of the study.

There was significant progress in the third quarter with regard to construction of the new manufacturing facility located in Austin Texas. During the quarter the building walls, structural steel, and roofing were installed. Build out of the interior was started in administrative and lab spaces, and the building was prepared for installation of clean rooms. Final engineering designs were completed for the manufacturing spaces with clean room construction scheduled to commence in Q4 2015. All activities are on schedule per the current project plan with anticipated building completion in March of 2016 and validation of product in July 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 September 30, 2015, we have recorded total research and development expenses, including share-based compensation, of \$90.9 million. Our total research and development expenses for the three months and nine months ended September 30, 2015 were \$9.7 million and \$20.9 million, respectively, compared to \$4.3 million and \$9.9 million for the three months and nine months ended September 30, 2014, respectively. Share-based compensation accounted for \$0.7 million and \$1.7 million for the three months and nine months ended September 30, 2015, respectively, compared to \$2.3 million and \$2.8 million for the three months and nine months ended September 30, 2014, respectively.

Research and development expenses, as a percentage of total operating expenses for the three months and nine months ended September 30, 2015 were 90% and 82%, respectively, compared to 62% and 65% for the three months and nine months ended September 30, 2014, respectively. The percentages, *excluding* stock-based compensation, for the three months and nine months ended September 30, 2015 were 91% and 87%, respectively, compared to 92% and 88% for the three months and nine months ended September 30, 2014, respectively.

As planned, our clinical costs will increase as we advance Xilonix™ as an anti-cancer therapy for treating last-line metastatic colorectal cancer, under a regulatory path through Phase III clinical trials in Europe and the US and when we expand the studies to South America, Australia and Canada, with all territories expected to be active by the end of 2015. Our clinical study underway in Europe that is being regulated by the European Medicines Agency ("EMA") have completed enrollment in August, 2015. Depending on the outcome of this study, submission for marketing approval with the EMA could take place by the year ended 2015, 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 phase 1 and 2 clinical study of novel True Human™ therapeutic antibody for treating serious infections due to *Staphylococcus aureus* in the U.S. We expect to expand this study to Europe, South Korea and Taiwan by the end of 2015. 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 and 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.

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 and nine months ended September 30, 2015 were \$1.1 million and \$4.5 million, respectively, compared to \$2.6 million and \$5.5 million for the three months and nine months ended September 30, 2014, respectively. Share-based compensation accounted for \$0.2 million and \$1.7 million for the three months and nine months ended September 30, 2015, respectively, compared to \$0.3 million and \$2.2 million for the three months and nine months ended September 30, 2014, 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 Quarterly Report on Form 10-Q, 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 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 initial public offering 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 these periods 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 September 30,		Nine Months Ended September 30,				
	2015	2014	2015		2014		
Weighted-average grant date fair value per share	\$16.91	\$15.00	\$17.99		\$10.46		
Expected volatility	66%	70%	66% –	71%	70% –	73%	
Risk-free interest rate	1.75%–	1.93%	2.96%	1.07%–	2.42%	0.69%–	2.96%
Expected life (in years)	10	10	3 –	10	5 –	10	
Dividend yield	–	–	–	–	–	–	

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.

Results of Operations**Revenue**

We did not record any revenue during the three months and nine months ended September 30, 2015 and 2014.

Expenses*Research and Development*

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

	Three Months Ended		%	
	September 30, 2015	September 30, 2014	Increase (Decrease)	Increase (Decrease)
Salaries and related expenses	\$ 1,581	\$ 969	\$ 612	63 %
Laboratory and manufacturing supplies	1,141	784	357	46 %
Clinical trials and sponsored research	5,059	1,660	3,399	205 %
Stock-based compensation	701	255	446	175 %
Other	1,249	673	576	86 %
Total	\$ 9,731	\$ 4,341	\$ 5,390	124 %

	Nine Months Ended		%	
	September 30, 2015	September 30, 2014	Increase (Decrease)	Increase (Decrease)
Salaries and related expenses	\$ 4,558	\$ 2,768	\$ 1,790	65 %
Laboratory and manufacturing supplies	3,180	1,723	1,457	85 %
Clinical trials and sponsored research	8,463	2,740	5,723	209 %
Stock-based compensation	1,677	730	947	130 %
Other	3,018	1,976	1,042	53 %
Total	\$ 20,896	\$ 9,937	\$ 10,959	110 %

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 124% to \$9.7 million for three months ended September 30, 2015 compared to \$4.3 million for the three months ended September 30, 2014. Research and development expenses increased by 110% to \$20.9 million for the nine months ended September 30, 2015 compared to \$9.9 million for the nine months ended September 30, 2014.

The increase in research and development expenses for the three months ended September 30, 2015 compared to the three months ended September 30, 2014 was due to a continued increase of employees working at the Company from 68 to 73 and salary increase for current employees. Laboratory and manufacturing supplies also increased due to the increase of the research activities as well as quality control activities. The sharp increase of clinical trials and sponsored research results primarily from the clinical trial started in Europe and the US. In the meantime, stock-based compensation increased due to issuing stock options to new employees and the expenses related to the employees' options awarded in 2015.

Compared to the nine months ended September 30, 2014, research and development expenses doubled for the nine months ended September 30, 2015. This increase was principally due to a \$5.7 million increase in clinical trial

activities, mainly in Europe and the US. The laboratory and manufacturing supplies increased due to manufacturing processing development activities. Labor costs also increased due to current employees' salary increase and the growing size of the workforce, increases in stock-based compensation due to the stock options awarded in the second half of 2014 and the continuing vesting of such awards in 2015.

General and Administrative

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

	Three Months Ended		Increase (Decrease)	% Increase (Decrease)	
	September 30, 2015	2014			
Salaries and related expenses	\$ 235	\$ 116	\$ 119	103	%
Patent filing expense	172	93	79	85	%
Stock-based compensation	185	2,269	(2,084)	(92	%)
Professional fees	58	65	(7)	(11	%)
Other	433	96	337	351	%
	\$ 1,083	\$ 2,639	(\$ 1,556)	(59	%)
	Nine Months Ended		Increase (Decrease)	% Increase (Decrease)	
	September 30, 2015	2014			
Salaries and related expenses	\$ 844	\$ 410	\$ 434	106	%
Patent filing expense	655	348	307	88	%
Stock-based compensation	1,678	4,243	(2,565)	(60	%)
Professional fees	480	121	359	297	%
Other	885	330	555	168	%
	\$ 4,542	\$ 5,452	(\$ 910)	(17	%)

General and administrative expenses decreased by 59% to \$1.1 million for the three months ended September 30, 2015 compared to \$2.6 million for the three months ended September 30, 2014. General and administrative expenses decreased by 17% to \$4.5 million for the nine months ended September 30, 2015 compared to \$5.5 million for the nine months ended September 30, 2014.

The three months decrease was primarily related to the stock-based compensation expenses of \$2.3 million in 2014 due to the immediately-vested grant of stock options to board members and employees in the second half of 2014. The salary and related costs increased primarily due to new employees in the general and administrative department. Patent filing expenses also increased due to the increase of worldwide patent certification activities.

The nine months decrease was also primarily due to the stock-based compensation expenses in connection with the stock options to board members, consultants and employees in the second half of 2014. The increase of professional fees, which partially offset the decrease, was due to an increase in legal fees after the Company became a public entity. Salaries and related costs increased resulted from current employees' salary increase, the growing size of the workforce, and a bonus payment to an executive officer.

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 September 30, 2015, we have funded our operations principally through the private placement of equity securities and our initial public offering, which have provided aggregate cash proceeds of approximately \$206.4 million. The following table summarizes our sources and uses of cash (in thousands):

	Nine Months Ended	
	September 30,	
	2015	2014
Net cash (used in) provided by:		
Operating activities	\$(22,613)	\$(8,249)
Investing activities	(6,646)	(846)
Financing activities	77,468	17,351
Effect of foreign exchange rate on cash and cash equivalents	142	(4)
Net change in cash and cash equivalents	\$48,351	\$8,252

During the nine months ended September 30, 2015 and 2014, our operating activities used net cash of \$22.6 million and \$8.2 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 nine months ended September 30, 2015 as compared to the nine months ended September 30, 2014 was due to the increase in clinical trial activities in Europe and the growing size of workforce.

During the nine months ended September 30, 2015 and 2014, our investing activities used net cash of \$6.6 million and \$0.8 million, respectively. We spent approximately \$4.7 million more on the construction of our new manufacturing facility during the nine months ended September 30, 2015 compared to the nine months ended September 30, 2014. We also spent \$1.1 million more on purchases of scientific equipment during the nine months ended September 30, 2015, compared to the nine months ended September 30, 2014.

During the nine months ended September 30, 2015 and 2014, our financing activities provided net cash proceeds of \$77.5 million and \$17.4 million, respectively. During the nine months ended September 30, 2015, we received IPO proceeds of \$72.2 million and incurred offering costs of \$1.6 million, which consisted of direct incremental legal, accounting and other professional service fees related to our IPO. Also, during the nine months ended September 30, 2015, investors exercised warrants to purchase a total of 373,332 shares of our common stock at an exercise price of \$15.00 per share for a total of approximately \$5.6 million in net proceeds, and exercised stock option to purchase a total of 133,000 shares of our common stock for a total of approximately \$0.7 million in net proceeds. In January 2015, we received previously outstanding subscription receivable in the amount of \$0.4 million.

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 September 30, 2015, our principal sources of liquidity were our cash and cash equivalents, which totaled approximately \$105.7 million.

On April 14, 2015, our registration statement on Form S-1 (File No. 333-201813) was declared effective by the SEC for our initial public offering pursuant to which we sold an aggregate of 4,000,000 shares of our common stock at a price of \$19.00 per share. The offering commenced as of April 14, 2015 and did not terminate before all of the securities registered in the registration statement were sold. On April 17, 2015, we closed the sale of such shares, resulting in net proceeds to us of approximately \$70.6 million after deducting underwriting discounts and commissions of \$3.8 million and other offering expenses of approximately \$1.6 million. No payments were made by us to directors, officers or persons owning ten percent or more of our common stock or to their associates, or to our affiliates. There has been no material change in the planned use of proceeds from our initial public offering as described in our final prospectus filed with the Securities and Exchange Commission on April 16, 2015 pursuant to Rule 424(b).

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 \$164 thousand and \$139 thousand for the three months ended September 30, 2015 and 2014, respectively. On February 28, 2015, we extended the lease for another 4 years. The future minimum lease payments are as follows as of September 30, 2015 (in thousands):

Contractual Obligations	Total	Less than 1 Year	1 - 3 Years	3 - 5 Years	More than 5 Years
Operating facility leases	\$ 1,567	\$ 445	\$ 925	\$ 197	\$ —
Total contractual obligations	\$ 1,567	\$ 445	\$ 925	\$ 197	\$ —

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

There was no change in our internal control over financial reporting that occurred during the period covered by this Quarterly Report on Form 10-Q 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

We are not currently a part to any material litigating or other material legal proceedings.

Item 1A. Risk Factors

There have been no material changes in the risk factors previously disclosed in our final prospectus filed with the SEC on April 16, 2015.

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

(a) Recent Sales of Unregistered Equity Securities

During the period between July 1, 2015 and September 30, 2015, one investor exercised a warrant to purchase a total of 12,000 shares of our common stock at price of \$2.50 per share for a total of approximately \$30 thousand in net proceeds from this exercised warrant.

(b) Use of Proceeds from IPO

On April 14, 2015, our registration statement on Form S-1 (File No. 333-201813) was declared effective by the Securities and Exchange Commission for our initial public offering pursuant to which we sold an aggregate of 4,000,000 shares of our common stock to investors at a price of \$19.00 per share. W.R. Hambrecht + Co., Inc. acted as the sole underwriter. The offering commenced as of April 14, 2015 and did not terminate before all of the securities registered in the registration statement were sold. On April 17, 2015, we closed the sale of such shares, resulting in net proceeds to us of approximately \$70.6 million after deducting underwriting discounts and commissions of \$3.8 million and other offering expenses of approximately \$1.6 million. No payments were made by us to directors, officers or persons owning ten percent or more of our common stock or to their associates, or to our affiliates.

There has been no material change in the planned use of proceeds from our initial public offering as described in our final prospectus filed with the Securities and Exchange Commission on April 16, 2015 pursuant to Rule 424(b). We are holding the balance of the net proceeds from the IPO in a bank account at CIBC USD account.

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.INS* XBRL Instance Document.

101.SCH* XBRL Taxonomy Extension Schema Document.

101.CAL* XBRL Taxonomy Extension Calculation Linkbase Document.

101.DEF* XBRL Taxonomy Extension Definition Linkbase Document.

101.LAB* XBRL Taxonomy Extension Label Linkbase Document.

101.PRE* XBRL Taxonomy Extension Presentation Linkbase Document

*Exhibits filed herewith.

**Exhibits furnished herewith.

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: November 13, 2015 **XBIOTECH INC.**

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

Date: November 13, 2015 By: /s/ Queena Han
Queen Han
Vice President, Finance and Human Resources, and Secretary
(Principal Financial Officer and Principal Accounting Officer)

EXHIBIT INDEX

Exhibit Number Description of Document

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