

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

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 (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		Nine Months Ended	
	September 30,		September 30,	
	2015	2014	2015	2014
	(unaudited)	(unaudited)	(unaudited)	(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