

XBiotech Inc.  
Form 10-Q  
August 08, 2017

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM 10-Q**

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

**For the quarterly period ended June 30, 2017**

**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**

**(State or other jurisdiction of incorporation or organization)**      **(IRS Employer 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      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, a smaller reporting company, or an emerging growth company. See the definitions of “large accelerated filer,” “accelerated filer,” “smaller reporting company” and “emerging growth 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
		Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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 August 8, 2017, there were 35,419,772 shares of the Registrant's common stock issued and outstanding.



**XBIOTECH INC**

**INDEX**

**PART I—FINANCIAL INFORMATION**

<u>Item 1.</u>	<u>Consolidated Financial Statements</u>	<u>6</u>
	<u>Consolidated Balance Sheets as of June 30, 2017 (unaudited) and December 31, 2016</u>	<u>6</u>
	<u>Consolidated Statements of Operations for the Three Months and Six Months Ended June 30, 2017 (unaudited) and 2016 (unaudited)</u>	<u>7</u>
	<u>Consolidated Statements of Comprehensive Loss for the Three Months and Six Months Ended June 30, 2017 (unaudited) and 2016 (unaudited)</u>	<u>8</u>
	<u>Consolidated Statements of Cash Flows for Six Months Ended June 30, 2017 (unaudited) and 2016 (unaudited)</u>	<u>9</u>
	<u>Notes to Consolidated Financial Statements (unaudited)</u>	<u>10</u>
<u>Item 2.</u>	<u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>16</u>
<u>Item 3.</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	<u>21</u>
<u>Item 4.</u>	<u>Controls and Procedures</u>	<u>21</u>

**PART II—OTHER INFORMATION**

<u>Item 1.</u>	<u>Legal Proceedings</u>	<u>23</u>
<u>Item 1A.</u>	<u>Risk Factors</u>	<u>23</u>
<u>Item 2.</u>	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	<u>23</u>
<u>Item 3.</u>	<u>Defaults Upon Senior Securities</u>	<u>24</u>
<u>Item 4.</u>	<u>Mine Safety Disclosures</u>	<u>24</u>
<u>Item 5.</u>	<u>Other Information</u>	<u>24</u>
<u>Item 6.</u>	<u>Exhibits</u>	<u>25</u>

**SIGNATURES**

## 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,” “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. 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, 2016 filed with the SEC on March 16, 2017, 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.





**XBiotech Inc.**

## Consolidated Balance Sheets

(in thousands, except share data)

	June 30, 2017 (unaudited)	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	\$45,949	\$34,324
Prepaid expenses and other current assets	1,352	2,606
Total current assets	47,301	36,930
Property and equipment, net	30,540	10,142
Building construction in progress	-	19,978
Total assets	\$77,841	\$67,050
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	\$3,385	\$4,431
Accrued expenses	1,278	3,532
Total current liabilities	4,663	7,963
Long-term liabilities:		
Deferred rent	22	23
Total liabilities	4,685	\$7,986
Shareholders' equity:		
Preferred stock, no par value, unlimited shares authorized, no shares outstanding	-	-
Common stock, no par value, unlimited shares authorized, 35,419,772 and 32,627,691 shares outstanding at June 30, 2017 and December 31, 2016, respectively	276,589	242,419
Accumulated other comprehensive income	(326 )	57
Accumulated deficit	(203,107)	(183,412)
Total shareholders' equity	73,156	59,064
Total liabilities and shareholders' equity	\$77,841	\$67,050

*See accompanying notes.*

**XBiotech Inc.**

## Consolidated Statements of Operations

(in thousands, except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017 (unaudited)	2016 (unaudited)	2017 (unaudited)	2016 (unaudited)
Operating expenses:				
Research and development	\$7,399	\$11,216	\$15,587	\$19,028
General and administrative	2,289	2,399	4,372	4,835
Total operating expenses	9,688	13,615	19,959	23,863
Loss from operations	(9,688 )	(13,615 )	(19,959 )	(23,863 )
Other income (loss):				
Interest income	114	-	164	-
Foreign exchange gain (loss)	441	(7 )	99	(16 )
Total other income (loss)	555	(7 )	263	(16 )
Net loss	\$(9,133 )	\$(13,622 )	\$(19,696 )	\$(23,879 )
Net loss per share—basic and diluted	\$(0.26 )	\$(0.42 )	\$(0.57 )	\$(0.74 )
Shares used to compute basic and diluted net loss per share	35,320,499	32,378,412	34,311,690	32,333,199

*See accompanying notes.*

Consolidated Statements of Comprehensive Loss

(in thousands)

	Three		Six	
	Months Ended June		Months Ended June	
	30,	30,	30,	30,
	2017	2016	2017	2016
	(unaudited)	(unaudited)	(unaudited)	(unaudited)
Net loss	\$ (9,133)	\$ (13,622 )	\$ (19,696)	\$ (23,879 )
Foreign currency translation adjustment	(493 )	(26 )	(383 )	12
Comprehensive loss	\$ (9,626)	\$ (13,648 )	\$ (20,079)	\$ (23,867 )

*See accompanying notes.*



**XBiotech Inc.**

## Consolidated Statements of Cash Flows

(in thousands)

	Six Months Ended June 30, 2017      2016 (unaudited)(unaudited)	
Operating activities		
Net loss	\$(19,696)	\$(23,879 )
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	592	350
Share-based compensation expense	896	2,914
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	1,255	460
Accounts payable	(1,167 )	1,536
Accrued expenses	(2,254 )	416
Deferred rent	(2 )	5
Net cash used in operating activities	(20,376)	(18,198 )
Investing activities		
Purchase of property and equipment	(890 )	(3,602 )
Expenditure on building construction	-	(5,172 )
Net cash used in investing activities	(890 )	(8,774 )
Financing activities		
Issuance of common stock and warrants, net	32,620	-
Issuance of common stock under stock option plan	654	707
Net cash provided by financing activities	33,274	707
Effect of foreign exchange rate on cash and cash equivalents	(383 )	12
Net change in cash and cash equivalents	11,625	(26,253 )
Cash and cash equivalents, beginning of period	34,324	91,051
Cash and cash equivalents, end of period	\$45,949	\$ 64,798
Supplemental Information:		
Accrued purchases of property and equipment	122	581
Accrued expenditure on building construction	-	1,550

*See accompanying notes.*



## **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 Switzerland AG, a wholly-owned subsidiary of the Company, was incorporated in Zug, Switzerland in August 2010. XBiotech Japan K.K., a wholly-owned subsidiary of the Company, was incorporated in Tokyo, Japan in March 2013. XBiotech Germany GmbH, a wholly-owned subsidiary of the Company, was incorporated in Germany in January 2014. The Company’s headquarters are located in Austin, Texas.

XBiotech Inc. (“XBiotech” or the “Company”) is a pre-market biopharmaceutical company engaged in discovering and developing True Human™ monoclonal antibodies for treating a variety of diseases. True Human™ monoclonal antibodies are those which occur naturally in human beings—as opposed to being derived from animal immunization or otherwise engineered. The Company believes that naturally occurring monoclonal antibodies have the potential to be safer and more effective than their non-naturally occurring counterparts. XBiotech is focused on developing its True Human™ pipeline and manufacturing system. The Company’s pipeline consists of product candidates at various stages of development across an array of indications including oncology, dermatology, and other inflammatory conditions such as peripheral vascular disease and type 2 diabetes.

### **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 (“US GAAP”). In the opinion of management, the accompanying consolidated financial statements reflect all adjustments (consisting only of normal recurring items) considered necessary to present fairly the Company’s financial position at June 30, 2017 and December 31, 2016, the results of its operations and comprehensive loss for the six month periods ended June 30, 2017 and 2016, and the cash flows for the six month periods ended June 30, 2017 and 2016.

#### **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 U.S. 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. After the initial public offering, the fair market value is calculated by using the closing price of the Company's common stock as reported by NASDAQ.

### **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.

## 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, which 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. The Company accounts for forfeitures as they occur rather than on an estimated basis.

Share-based compensation expense recognized for the three and six months ended June 30, 2017 and 2016 was included in the following line items on the Consolidated Statement of Operations (in thousands).

	Three Months Ended June 30, 2017		Six Months Ended June 30, 2016	
	2017	2016	2017	2016
Research and development	\$(273 )	\$587	\$21	\$1,184
General and administrative	1,171	511	1,601	1,730
Total share-based compensation expense	\$898	\$1,098	\$1,622	\$2,914

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 June 30,				Six Months Ended June 30,			
	2017		2016		2017		2016	
Dividend yield	-	-	-	-	-	-	-	-
Expected volatility	67%	65%	70%	70%	65%	67%	65%	70%
Risk-free interest rate	1.83%-	1.97%	1.16%-	1.51%	1.83%-	2.41%	1.16%-	1.82%

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Expected life (in years)	5.38 - 6	5.25 - 6.25	5.38 - 10	5 - 10
Weighted-average grant date fair value per share	4.66	8.17	4.85	6.64

**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, Japanese 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 June 30, 2017 and December 31, 2016, 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 June 30, 2017 and December 31, 2016, 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, vehicles and building 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 7 years
- Office equipment 5 years
- Leasehold improvements Shorter of asset's useful life or remaining lease term
- Scientific equipment 5 years
- Vehicles 5 years
- Building 39 years

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.

### **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 June 30, 2017.

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

### **Recent Accounting Pronouncements**

In February 2016, the FASB issued ASU No. 2016-02, “Leases.” ASU 2016-02 requires companies that lease assets to recognize a right-of-use asset and a lease liability, initially measured at the present value of the lease payments, in its balance sheet. The pronouncement will also require additional disclosures about the amount, timing and uncertainty of cash flows arising from leases. This pronouncement is effective for fiscal years, and interim periods within those years, beginning after December 15, 2018, and early adoption is permitted. Management is currently evaluating the impact of this pronouncement on XBiotech’s consolidated financial statements.

### **3. Common Stock**

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

From January through December 2016, 204 thousand shares of common stock were issued upon the exercise of stock options at a price of \$0.74 to \$19.09 per share for total proceeds of \$1.1 million.

From November through December 2016, under the Common Stock Sales Agreement with H.C. Wainwright & Co. LLC, the Company sold 145 thousand shares of common stock at a price between \$13.60 to \$14.17 per share for total proceeds of \$1.8 million.

In February 2017, under the Common Stock Sales Agreement with H.C. Wainwright & Co. LLC, the Company sold 87 thousand shares of common stock at a price between \$12.09 to \$12.37 per share for total proceeds of \$1.0 million.

In March 2017, the Company sold 2.4 million shares of common stock for total proceeds of approximately \$31.6 million from investors. Also, in March 2017, 66 thousand shares of common stock were issued upon the exercise of stock options at the price between \$2.50 to \$14.71 per share for total proceeds of \$315 thousand.

From April to June 2017, 204 thousand shares of common stock were issued upon the exercise of stock options at a price of \$0.93 to \$10 per share for a total of \$454 thousand.

### **4. Common Stock Options**

On November 11, 2005 and April 1, 2015, the board of directors of the Company adopted stock option plans (“the Plans”) 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 an 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. Options held by non-employee Directors have an exercise period coterminous with the term of the options.

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 Plans is as follows:

	Options	Exercise Price	Weighted-Average Exercise Price
Options outstanding at December 31, 2016	5,188,658	\$0.52-\$21.99	\$ 8.49
Granted	880,000	4.24 -12.62	4.85
Exercised	(387,167 )	0.93 -14.71	2.27
Forfeitures	(235,370 )	0.94 -21.99	14.26
Options outstanding at June 30, 2017	5,446,121	\$0.94-\$21.99	\$ 8.09

As of June 30, 2017, there was approximately \$3.5 million of unrecognized compensation cost, related to stock options granted under the Plans which will be amortized to stock compensation expense over the next 2.53 years.

## **5. Commitments and Contingencies**

XBiotech Corporate officers, Queena Han (VP of Finance) and John Simard (President and CEO), XBiotech Inc., and certain directors were named defendants in securities class action civil suits filed in federal court at the U.S. District Court for the Western District of Texas, in Austin, Texas and state court at the Los Angeles County Superior Court, in California. In the California action, the underwriter WR Hambrecht & Co., LLC was also named as a defendant. These civil suits were filed on December 1, 2015. The foundation for both suits are similar in that the plaintiffs allege the officers of the Company made false and misleading statements, violating the securities laws, in the IPO documents in April 2015. Specifically, these alleged false statements in the IPO documents are in relation to the European Phase III clinical trial for Xilonix™. The allegations focus on a press release posted by XBiotech on November 23, 2015, explaining certain issues with patient data. Plaintiffs allege the company knew of these issues during the IPO and neglected to disclose them in supporting documentation filed with the Security and Exchange Commission (SEC). As a result of the news release, XBiotech (traded on the NASDAQ) stock declined. The resulting securities class action lawsuits are seeking relief for plaintiffs who report financial losses due to the alleged false and misleading statements. In September 2016, a stay was granted in the California case. Plaintiffs were, at that time, left with the opportunity to re-file in Texas prior to the decision on the motion to dismiss. Plaintiffs did not re-file in Texas before the case was dismissed with prejudice in October 2016. Plaintiffs sought to re-open the case in California. A hearing to address whether the case should be dismissed, was scheduled June 7, 2017. At the hearing, counsel for XBiotech argued that California was a forum non conveniens given the nexus of the allegations in the suit took place in Texas. The judge granted the forum non conveniens motion, finding that the case does not belong in California. As a result, the case is stayed rather than dismissed per California procedural rules. Plaintiffs were compelled to re-file in Texas.

A status conference on the California case is tentatively scheduled for January 2018. Meanwhile, the plaintiffs re-filed their suit in Travis County district court, located in Austin, Texas, on July 6, 2017. A hearing date has yet to be scheduled in this matter.



## **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 Inc. (“XBiotech” or the “Company”) is a pre-market biopharmaceutical company engaged in discovering and developing True Human™ monoclonal antibodies for treating a variety of diseases. True Human™ monoclonal antibodies are those which occur naturally in human beings—as opposed to being derived from animal immunization 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. XBiotech is focused on developing its True Human™ pipeline and manufacturing system.

We have never been profitable and, as of June 30, 2017, we had an accumulated deficit of \$203.1 million. We had net losses of \$9.1 million and \$19.7 million for the three months and six months ended June 30, 2017, respectively, compared to \$13.6 million and \$23.9 million for the three months and six months ended June 30, 2016, respectively. We expect to incur significant 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 continue to operate as a public company. We will need to generate significant revenues to achieve profitability, and we may never do so. As of June 30, 2017, we had 60 employees compared to 103 as of March 31, 2017. This decrease was due to a re-organization of the Company that occurred following the recent material events surrounding the Phase 3 oncology studies.

#### **Recent Events:**

#### **Clinical Regulatory Developments**

The Company’s Phase III symptomatic colorectal cancer study has been completed and XBiotech proceeded with the submission of a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) in March 2016. In May 2017, the Company announced that it received a negative opinion from the EMA’s Committee for Medicinal Products for Human Use (“CHMP”) for the MAA in Europe. XBiotech is proceeding with the EMA’s re-examination procedure in which new Rapporteurs will be assigned to reevaluate the initial opinion. The Company has retained European counsel and regulatory specialists in Europe to manage the re-examination process, who is following the standard protocol and timetable set by the EMA.

In June 2017 XBiotech reported discontinuation of its second Phase III study, a double-blind placebo controlled study for improving survival in metastatic colorectal cancer, following the Independent Data Monitoring Committee's (IDMC) second prospectively planned, unblinded interim analysis at 75% of events in the study. The IDMC had no safety concerns from the unblinded analysis. However, the committee recommended the early termination of the study since the findings were not sufficient to meet efficacy or the threshold for continuation, which involved a prospectively defined acceptance boundary for the interim analysis. XBiotech is currently conducting full data analyses, as stratification of the data may identify subpopulations that benefited from therapy.

Based on the positive, top-line results announced earlier this year in two Phase II studies, one which evaluated MABp1 for the treatment of Hidradenitis Suppurativa and one using the Company's proprietary 514G3 True Human antibody for the treatment of *Staphylococcus aureus* bloodstream infections, plans for advanced studies in these indications is on-going. We are seeking end of Phase 2 meetings with the FDA to help guide the development of special protocol assessments (SPA), which are submitted to the FDA to enable better agreement on what will be sufficient data to seek product registration.

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 clinical trials, is expected to depend on the amount and timing of cash receipts from future collaboration or product sales and/or financing transactions. The Company believes that its cash and cash equivalents of \$45.9 million at June 30, 2017 will enable the Company to achieve several major inflection points, including potential marketing authorization in Europe depending on the outcome of the re-examination procedure, advanced clinical studies in certain indication(s), as well as on-going R&D efforts for the Company's pre-clinical pipeline. Based on our research and development plans and our timing expectations related to the progress of our programs, we expect that our cash and cash equivalents as of June 30, 2017 will enable us to fund our operating expenses and capital expenditure requirements through 2018. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect.

## 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 June 30, 2017, we have recorded total research and development expenses, including share-based compensation, of \$159.2 million. Our total research and development expenses for the three months and six months ended June 30, 2017 were \$7.4 million and \$15.6 million, respectively, compared to \$11.2 million and \$19.0 million for the three months and six months ended June 30, 2016, respectively. Share-based compensation accounted for (\$0.3) million and \$21 thousand for the three months and six months ended June 30, 2017, respectively, compared to \$0.6 million and \$1.2 million for the three months and six months ended June 30, 2016, respectively.

Research and development expenses, as a percentage of total operating expenses for the three months and six months ended June 30, 2017 were 76% and 78%, respectively, compared to 82% and 80% for the three months and six months ended June 30, 2016, respectively. The percentages, *excluding* stock-based compensation, for the three months and six months ended June 30, 2017 were 87% and 85%, respectively, compared to 88% and 87% for the three months and six months ended June 30, 2016, respectively.

The clinical research and development costs may decrease going forward with the completion of all clinical studies to date. Although, expenses could increase due to potential marketing approval of our lead product candidate in Europe based on the outcome of the re-examination procedure and related commercialization costs, as well as, the potential of pursuing advanced clinical studies in various indications.

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 research and development 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 six months ended June 30, 2017 were \$2.3 million and \$4.4 million, respectively, compared to \$2.4 million and \$4.8 million for the three months and six months ended June 30, 2016, respectively. Share-based compensation accounted for \$1.2 million and \$1.6 million for the three months and six months ended June 30, 2017, respectively, compared to \$0.5 million and \$1.7 million for the three months and six months ended June 30, 2016, respectively.

General and administrative expenses, as a percentage of total operating expenses for the three months and six months ended June 30, 2017 were 24% and 22%, respectively, compared to 18% and 20% for the three months and six months ended June 30, 2016, respectively. The percentages, *excluding* stock-based compensation, for the three months and six months ended June 30, 2017 were 13% and 15%, respectively, compared to 15% and 15% for the three months and six months ended June 30, 2016, respectively.

### Critical Accounting Policies

The preparation of financial statements in conformity with generally accepted accounting principles requires us to make judgments, estimates and assumptions in the preparation of our consolidated financial statements and accompanying notes. Actual results could differ from those estimates. We believe there have been no significant changes in our critical accounting policies as discussed in our Annual Report on Form 10-K for the year ended December 31, 2016.

### Results of Operations

#### Revenue

We did not record any revenue during the three months and six months ended June 30, 2017 and 2016.

#### Expenses

##### Research and Development

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

	Three Months Ended June 30,		Increase	% Increase
	2017	2016	(Decrease)	(Decrease)
Salaries and related expenses	\$1,770	\$1,980	\$(211 )	(11 %)
Laboratory and manufacturing supplies	780	2,762	(1,982 )	(72 %)



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Clinical trials and sponsored research	3,785	4,657	(872 )	(19 %)
Stock-based compensation	(273 )	587	(860 )	(147 %)
Other	1,337	1,230	108	9 %
Total	\$7,399	\$11,216	\$(3,817 )	(34 %)

	Six Months Ended		Increase	% Increase
	June 30,			
	2017	2016	(Decrease)	(Decrease)
Salaries and related expenses	\$3,983	\$3,837	\$ 146	4 %
Laboratory and manufacturing supplies	2,012	3,538	(1,526 )	(43 %)
Clinical trials and sponsored research	6,941	8,313	(1,372 )	(17 %)
Stock-based compensation	21	1,184	(1,163 )	(98 %)
Other	2,630	2,156	474	22 %
Total	\$15,587	\$19,028	\$(3,441 )	(18 %)

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 decreased by 34% to \$7.4 million for the three months ended June 30, 2017 compared to \$11.2 million for the three months ended June 30, 2016. Research and development expenses decreased by 18% to \$15.6 million for the six months ended June 30, 2017 compared to \$19.0 million for the six months ended June 30, 2016.

The three month decrease in research and development expenses was mainly due to a \$2.0 million decrease in laboratory and manufacturing supplies expense, due to a reduction in clinical trial drug manufacturing. In addition there was a decrease in clinical trials and sponsored research expense due to the slow down of a global trial. Stock-based compensation expenses also decreased due to the forfeiture of terminated employees' stock option.

Compared to the six months ended June 30, 2016, the research and development expense decrease in the six months ended June 30, 2017 was primarily caused by the decrease in laboratory and manufacturing supplies expense. The clinical trials and sponsored research expense decrease was principally due to the reduced expense accrual and as a result of the slow down of a global trial.

#### *General and Administrative*

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

	Three Months Ended June 30,		Increase (Decrease)	% Increase (Decrease)
	2017	2016		
Salaries and related expenses	\$297	\$386	\$ (89 )	(23 %)
Patent filing expense	171	207	(36 )	(17 %)
Stock-based compensation	1,171	511	660	129 %
Professional fees	312	768	(456 )	(59 %)
Other	338	527	(189 )	(36 %)
Total	\$2,289	\$2,399	\$ (110 )	(5 %)

	Six Months Ended June 30,		Increase (Decrease)	% Increase (Decrease)
	2017	2016		
Salaries and related expenses	\$765	\$913	\$ (148 )	(16 %)
Patent filing expense	357	353	4	1 %
Stock-based compensation	1,601	1,730	(129 )	(7 %)
Professional fees	728	860	(132 )	(15 %)

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Other	921	979	(58	)	(6	%)
Total	\$4,372	\$4,835	\$ (463	)	(10	%)

General and administrative expenses decreased by 5% to \$2.3 million for the three months ended June 30, 2017 compared to \$2.4 million for the three months ended June 30, 2016. General and administrative expenses decreased by 10% to \$4.4 million for the six months ended June 30, 2017 compared to \$4.8 million for the six months ended June 30, 2016.

The three months decrease was primarily related to a \$0.5 million decrease in public relations fees and legal fees. Other expenses also decreased including travel and recruiting activities. Stock-based compensation increased \$0.7 million due to the repurchase of stock options from a certain individual.

The six months decrease was principally due to the decrease in stock-based compensation, the reduction of our workforce and the public relations fees. The decrease in stock-based compensation is due to the grant of stock options to board members in 2016 Q1 that were immediately vested. Labor costs also decreased due to the reduction of our general and administrative workforce from 11 to 5.

***Other income (loss)***

The following table summarizes other income (loss) (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Interest income	114	-	164	-
Foreign exchange gain (loss)	441	(7)	99	(16)
Total	\$555	\$(7)	\$263	\$(16)

The interest income for the three months and six months ended June 30, 2017 is mainly from the interest generated from our Canadian bank account. Foreign exchange gain was mainly due to the fluctuation of the exchange rate between Euro and US dollar.

### 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 June 30, 2017, we have funded our operations principally through public offerings and private placements of equity securities, which have provided aggregate cash proceeds of approximately \$289.9 million. The following table summarizes our sources and uses of cash (in thousands):

	Six Months Ended June 30,	
	2017	2016
Net cash (used in) provided by:		
Operating activities	\$(20,376)	\$(18,198)
Investing activities	(890 )	(8,774 )
Financing activities	33,274	707
Effect of foreign exchange rate on cash and cash equivalents	(383 )	12
Net change in cash and cash equivalents	\$11,625	\$(26,253)

During the six months ended June 30, 2017 and 2016, our operating activities used net cash of \$20.4 million and \$18.2 million, respectively. The use of net cash in each of these periods primarily resulted from our net losses. The net loss from operations for the six months ended June 30, 2017 as compared to the six months ended June 30, 2016 decreased, but the prepayment for clinical trial and payment for bills related to previous period expense increased the cash used.

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During the six months ended June 30, 2017 and 2016, our investing activities used net cash of \$0.9 million and \$8.7 million, respectively. The use of cash during the six months ended June 30, 2017 was for the purchase of new research and development equipment. We spent approximately \$8.8 million on the construction of new facilities during the six months ended June 30, 2016.

During the six months ended June 30, 2017 and 2016, our financing activities provided net cash proceeds of \$33.3 million and \$0.7 million, respectively. During the six months ended June 30, 2017, we entered into subscription agreements with accredited investors, and sold 2.4 million common shares at \$13 per share for approximately \$31.6 million in net proceeds. Also, we sold 87 thousand shares under a Common Stock Sales Agreement with H.C. Wainwright & Co. LLC for net proceeds of approximately \$1.0 million. Employees exercised stock options to purchase a total of 271 thousand shares of common stock for a total of approximately \$0.8 million in net proceeds. During the six months ended June 30, 2016, employees exercised stock options to purchase a total of 150 thousand shares of common stock for a total of approximately \$0.7 million in net proceeds.

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 Food and Drug Administration or similar regulatory agencies in other countries and successfully commercialized. As of June 30, 2017, our principal sources of liquidity were our cash and cash equivalents, which totaled approximately \$45.9 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. On February 28, 2016, we extended the lease for another 4 years. The future minimum lease payments are as follows as of June 30, 2017 (in thousands):

<b>Contractual Obligations</b>	<b>Total</b>	<b>Less than 1 Year</b>	<b>1 - 3 Years</b>	<b>More than 3 years</b>
Operating facility leases	\$780	\$ 465	\$ 315	\$ —
Total contractual obligations	\$780	\$ 465	\$ 315	\$ —

Rent expense was \$186 thousand and \$180 thousand for the three months ended June 30, 2017 and 2016, respectively.

### 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 second quarter of the year ended December 31, 2017 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.

In September 2016, a stay was granted at the Superior Court for the State of California, Los Angeles County, in *Yogina Rezko v. XBiotech Inc., John Simard, Queena Han and WR Hambrecht & Co., LLC*, in light of the ongoing case, *Linh Tran v. XBiotech Inc., John Simard and Queena Han*, in the U.S. District Court for the Western District of Texas, leaving plaintiffs with an opportunity re-file a complaint in Texas. In October 2016, the Texas securities class action lawsuit was dismissed with prejudice. At the June 7, 2017 hearing at the Superior Court for the State of California, Los Angeles County, we were granted a motion on the grounds of forum non conveniens. The judge ruled that the case belonged in Texas, not in California. The case is nevertheless stayed, due to California procedural rules, and not dismissed. A status conference is tentatively scheduled for January 2018.

On July 6, 2017, plaintiffs proceeded to re-file in Travis County district court (located in Austin, Texas). A hearing date has yet to be scheduled. We are unable to estimate the outcome of the Texas state court matter or the resulting financial impact to us, if any.

### **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, 2016. 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, 2016, 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.

The following financial statements from the XBiotech Inc. Quarterly Report on Form 10-Q for the quarter ended June 30, 2017, 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.

**XBIOTECH INC.**

Date: August 8,  
2017

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

Date: August 8,  
2017

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

