

XBiotech Inc.  
Form 10-Q  
May 08, 2018

**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 March 31, 2018**

**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

Edgar Filing: XBiotech Inc. - Form 10-Q

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
		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 May 8, 2018, there were 35,519,772 shares of the Registrant's common stock issued and outstanding.

**XBIOTECH INC.**

**THREE MONTHS ENDED MARCH 31, 2018**

**INDEX**

**PART I—FINANCIAL INFORMATION**

Item 1. Consolidated Financial Statements

Consolidated Balance Sheets as of March 31, 2018 (unaudited) and December 31, 2017 6

Consolidated Statements of Operations for the Three Months Ended March 31, 2018 (unaudited) and 2017 (unaudited) 7

Consolidated Statements of Comprehensive Loss for the Three Months Ended March 31, 2018 (unaudited) and 2017 (unaudited) 8

Consolidated Statements of Cash Flows for the Three Months Ended March 31, 2018 (unaudited) and 2017 (unaudited) 9

Notes to Consolidated Financial Statements (unaudited) 10

Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations 17

Item 3. Quantitative and Qualitative Disclosures About Market Risk 21

Item 4. Controls and Procedures 21

**PART II—OTHER INFORMATION**

Item 1. Legal Proceedings 22

Item 1A. Risk Factors 22

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds 22

Item 3. Defaults Upon Senior Securities 23

Item 4. Mine Safety Disclosures 23

Item 5. Other Information 23

Item 6. Exhibits 24

**SIGNATURES**

EXHIBIT INDEX

3

## CAUTIONARY STATEMENTS REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements, which reflect our current views with respect to, among other things, our operations and financial performance. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q are forward-looking statements. You can identify forward-looking statements by terminology such as “may,” “will,” “should,” “would,” “could,” “expects,” “plans,” “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, 2017 filed with the SEC on March 16, 2018, 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)

	March 31, 2018 (unaudited)	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	\$28,416	\$31,768
Prepaid expenses and other current assets	1,333	1,564
Total current assets	29,749	33,332
Property and equipment, net	29,111	29,640
Total assets	\$58,860	\$62,972
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	\$1,160	\$1,730
Accrued expenses	1,274	1,062
Total current liabilities	2,434	2,792
Long-term liabilities:		
Deferred rent	16	18
Total liabilities	2,450	2,810
Shareholders' equity:		
Preferred stock, no par value, unlimited shares authorized, no shares outstanding	-	-
Common stock, no par value, unlimited shares authorized, 35,519,772 and 35,439,272 shares outstanding at March 31, 2018 and December 31, 2017, respectively	277,803	277,492
Accumulated other comprehensive loss	(762 )	(768 )
Accumulated deficit	(220,631 )	(216,562)
Total shareholders' equity	56,410	60,162
Total liabilities and shareholders' equity	\$58,860	\$62,972

*See accompanying notes.*

**XBiotech Inc.**

## Consolidated Statements of Operations

(in thousands, except share and per share data)

	Three Months Ended March 31,	
	2018	2017
	(unaudited)	(unaudited)
Operating expenses:		
Research and development	\$2,993	\$8,188
General and administrative	1,157	2,083
Total operating expenses	4,150	10,271
Loss from operations	(4,150 )	(10,271 )
Other income (loss):		
Interest income	64	49
Foreign exchange gain (loss)	17	(341 )
Total other income (loss)	81	(292 )
Net loss	\$(4,069 )	\$(10,563 )
Net loss per share—basic and diluted	\$(0.11 )	\$(0.32 )
Shares used to compute basic and diluted net loss per share	35,447,304	33,291,672

*See accompanying notes.*

**XBiotech Inc.**

Consolidated Statements of Comprehensive Loss

(in thousands)

	Three Months Ended March 31,	
	2018	2017
	(unaudited)	(unaudited)
Net loss	\$(4,069)	\$(10,563 )
Foreign currency translation adjustment	7	110
Comprehensive loss	\$(4,062)	\$(10,453 )

*See accompanying notes.*

**XBiotech Inc.**

## Consolidated Statements of Cash Flows

(in thousands)

	Three Months Ended March 31, 2018      2017 (unaudited)(unaudited)	
Operating activities		
Net loss	\$ (4,069 )	\$ (10,563 )
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	588	296
Share-based compensation expense	110	724
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	232	375
Accounts payable	(596 )	(1,835 )
Accrued expenses	212	(905 )
Deferred rent	(3 )	-
Net cash used in operating activities	(3,526 )	(11,908 )
Investing activities		
Purchase of property and equipment	(34 )	(607 )
Net cash used in investing activities	(34 )	(607 )
Financing activities		
Issuance of common stock and warrants, net	-	32,620
Issuance of common stock under stock option plan	201	93
Net cash provided by financing activities	201	32,713
Effect of foreign exchange rate on cash and cash equivalents	7	110
Net change in cash and cash equivalents	(3,352 )	20,308
Cash and cash equivalents, beginning of period	31,768	34,324
Cash and cash equivalents, end of period	\$ 28,416	\$ 54,632
Supplemental Information:		
Accrued purchases of property and equipment	25	101
Receivable on issuance of common stock under stock option plan	-	223

*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. 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, other inflammatory conditions, such as peripheral vascular disease, type 2 diabetes, and infectious diseases.

### **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 March 31, 2018 and December 31, 2017, the results of its operations and comprehensive loss for the three month periods ended March 31, 2018 and 2017, and the cash flows for the three month periods ended March 31, 2018 and 2017.

#### **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.

### **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 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. To determine the fair value of its common stock, the Company uses the closing price of the Company’s common stock as reported by NASDAQ. 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 months ended March 31, 2018 and 2017 was included in the following line items on the Consolidated Statements of Operations (in thousands).

	Three Months Ended March 31,	
	2018	2017
Research and development	\$88	\$294
General and administrative	22	430
Total share-based compensation expense	\$110	\$724

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

	Three Months Ended March 31,	
	2018	2017
Dividend yield	-	-



Edgar Filing: XBiotech Inc. - Form 10-Q

Expected volatility	67%	-	80%	65%	-	67%
Risk-free interest rate	2.38%	-	2.71%	2.11%	-	2.41%
Expected life (in years)	6.0	-	10	6.25	-	10
Weighted-average grant date fair value per share	\$3.02		\$8.24			

**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 March 31, 2018 and December 31, 2017, the Company did not have any assets or liabilities that are measured at fair value on a recurring basis. The carrying amounts reflected in the balance sheets for cash and cash equivalents, prepaid expenses and other current assets, accounts payable, and accrued expenses approximate their fair values at March 31, 2018 and December 31, 2017, 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 March 31, 2018.

## 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.

The GAAP guidance requires recognition of the impact of a tax position in our financial statements only if that position is more likely than not to be sustained upon examination by taxing authorities, based on the technical merits of the position. Any interest and penalties related to uncertain tax positions will be reflected in income tax expense. Determining the consolidated provision for income taxes involves judgments, estimates and the application of complex tax regulations. We are required to provide for income taxes in each of the jurisdictions where we operate, including estimated liabilities for uncertain tax positions. Although we believe that we have provided adequate liabilities for uncertain tax positions, the actual liability resulting from examinations by taxing authorities could differ from the recorded income tax liabilities and could result in additional income tax expense having a material impact on our consolidated results of operations. Changes of estimates in our income tax liabilities are reflected in our income tax provision in the period in which the factors resulting in the change to our estimate become known to us. We benefit from the tax credit incentives under the U.S. research and experimentation tax credit extended to taxpayers engaged in qualified research and experimental activities while carrying on a trade or business.

On December 22, 2017, the President of the United States signed into law the Tax Cuts and Jobs Act, or TCJA, tax reform legislation. The TCJA makes significant changes in U.S. tax law including a reduction in the corporate tax rates, changes to net operating loss carryforwards and carrybacks, and a repeal of the corporate alternative minimum

tax. The TCJA reduced the U.S. corporate tax rate from the current rate of 34 percent down to 21 percent starting on January 1, 2018. As a result of the TCJA, the Company was required to revalue deferred tax assets and liabilities at 21 percent. As of and for the year ended December 31, 2017, this revaluation resulted in a provision of \$4.5 million to income tax expense in continuing operations and a corresponding reduction in the valuation allowance. As a result, there was no impact to the Company's consolidated statements of comprehensive loss as a result of the reduction in tax rates.

As the Company does not have all of the necessary information to analyze all income tax effects of the TCJA, the Company will continue to make and refine calculations and estimates as additional information is obtained, which could potentially affect the provisional amounts relating to the deferred income taxes, including but not limited to deferred tax assets related to share-based compensation expenses. Where the Company has not yet been able to make reasonable estimates of the impact of certain elements, the Company has not recorded any amounts related to those elements and has continued accounting for them in accordance with ASC 740 on the basis of the tax laws in effect immediately prior to the enactment of the TCJA. The Company expects to complete a detailed analysis no later than the fourth quarter of 2018.

### **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**

### *Recently Issued Accounting Pronouncements*

In February 2016, the FASB issued final guidance that will change the accounting for leases, Accounting Standards Update (ASU) No. 2016-02, "Leases." The FASB issued final guidance that requires lessees to put most leases on their balance sheets but recognize expenses on their income statements in a manner similar to today's accounting. The guidance also eliminates today's real estate-specific provisions for all entities. The pronouncement will also require additional disclosures about the amount, timing and uncertainty of cash flows arising from leases. For calendar-year public business entities and certain calendar-year not-for-profit entities and employee benefit plans, the guidance is effective in 2019, and interim periods within that year, and early adoption is permitted. The adoption of this standard will require the Company to record its operating leases on the balance sheet. The Company is currently evaluating the impact of this pronouncement on the Company'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 at a net price of \$13.00 for total proceeds of approximately \$31.6 million from investors.

From January through December 2017, 290 thousand shares of common stock were issued upon the exercise of stock options at a price of \$2.50 to \$14.71 per share for a total of \$703 thousand.

From January through March 2018, 81 thousand shares of common stock were issued upon the exercise of stock options at a price of \$2.50 per share for total proceeds of \$201 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 the Plans 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, 2017	5,303,624	\$2.5-	\$21.99	7.69
Granted	208,500	4.01-	4.92	4.19
Exercised	(80,500 )	2.5		2.50
Forfeitures	(532,475 )	2.50-	19.09	5.56
Options outstanding at March 31, 2018	4,899,149	\$2.5-	\$21.99	7.80

As of March 31, 2018, there was approximately \$2.0 million of unrecognized compensation cost, related to stock options granted under the Plans which will be amortized to stock compensation expense over the next 2.16 years.

## 5. Commitments and Contingencies

On January 12, 2008, the Company entered a lease agreement to lease its facility in Austin, Texas, U.S. On September 15, 2010, the Company entered into a second lease agreement to lease additional space in Austin, Texas, U.S. On March 20, 2013, the company extended the lease for another 21 months with the same terms and rental rates as the current leases. On February 28, 2015, the Company extended the leases for another four years with two years early termination right. The future minimum lease payments are as follows as of March 31, 2018 (in thousands):

2018 \$354

2019 \$79

Rent expense was approximately \$200 thousand and \$186 thousand for the three months ended March 31, 2018 and 2017, respectively.

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 the Company, certain of its officers and directors and the underwriter for its 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 the Company and certain of its 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, the Company was 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.

The plaintiffs re-filed their suit in Travis County district court, located in Austin, Texas, on July 6, 2017. The Company subsequently removed the case to the U.S. District Court for the Western District of Texas. Following a recent Supreme Court decision holding that the types of claims asserted in this action are non-removable, the suit was remanded back to Travis County district court, where it remains pending. The Company believes the claims asserted in the case are without merit and intends to mount a vigorous defense.

## **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 March 31, 2018, we had an accumulated deficit of \$220.6 million. We had net losses of \$4.1 million and \$10.6 million for the three months ended March 31, 2018 and 2017, 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 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 March 31, 2018, we had 40 employees.

#### **Recent Events:**

The Company recently announced the launch of two separate Phase 2, open label, dose escalation studies evaluating a new subcutaneous formulation of the Company’s True Human™ monoclonal antibody, MABp1, in patients with moderate to severe Atopic Dermatitis (AD) and Hidradenitis Suppurativa (HS). Dose ranging of this subcutaneous formulation for MABp1 is planned to be studied in 4 week and 12 week open label treatment regimens for AD and HS, respectively. These findings will establish the basis for potential further randomized studies with the subcutaneous formulation.

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 \$28.0 million at March 31, 2018 will enable the Company to achieve some key inflection points, including 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 March 31, 2018 will enable us to fund our operating expenses and capital expenditure requirements through 2019. 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 March 31, 2018, we have recorded total research and development expenses, including share-based compensation, of \$173.0 million. Our total research and development expenses for the three months ended March 31, 2018 and 2017 were \$3.0 million and \$8.2 million, respectively. Share-based compensation accounted for \$0.1 million and \$0.3 million for the three months ended March 31, 2018 and 2017, respectively.

Research and development expenses, as a percentage of total operating expenses for the three months ended March 31, 2018 and 2017 were 72% and 80%, respectively. The percentages, excluding stock-based compensation, for the three months ended March 31, 2018 and 2017, were 72% and 83%, respectively.

Our clinical development costs decreased with the completion and discontinuation of our phase III colorectal cancer clinical trials under EMA and FDA jurisdictions, respectively.

The clinical development costs may increase going forward with the recent launch of the two phase 2 dermatology studies which may potentially be followed by more advanced studies and as we evaluate our pipeline and plan potential new studies.

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 ended March 31, 2018 and 2017 were \$1.2 million and \$2.1 million, respectively. Share-based compensation accounted for \$22 thousand and \$430 thousand for the three months ended March 31, 2018 and 2017, respectively.

General and administrative expense, as a percentage of total operating expenses for the three months ended March 31, 2018 and 2017 were 28% and 20%, respectively. The percentages, excluding stock-based compensation, for the three months ended March 31, 2018 and 2017, were 28% and 17%, 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, 2017.

### **Results of Operations**

#### ***Revenue***

We did not record any revenue during the three months ended March 31, 2018 and 2017.

*Expenses**Research and Development*

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

	Three Months		Increase	% Increase
	Ended March	Ended March		
	31,	31,		
	2018	2017	(Decrease)	(Decrease)
Salaries and related expenses	\$1,051	\$2,213	\$ (1,162 )	-53 %
Laboratory and manufacturing supplies	213	1,232	(1,019 )	-83 %
Clinical trials and sponsored research	8	3,155	(3,147 )	-100 %
Stock-based compensation	88	294	(206 )	-70 %
Other	1,633	1,294	339	26 %
Total	\$2,993	\$8,188	\$ (5,195 )	-63 %

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 \$5.2 million to \$3.0 million for the three months ended March 31, 2018, compared to \$8.2 million for the three months ended March 31, 2017. The decrease was due to a \$3.1 million decrease of clinical trial activities and sponsored research expense, related to the completion of all active trials. Labor costs also decreased due to the reduced size of the research and development workforce from 93 to 35. In addition, the decrease in laboratory and manufacturing supplies expense occurred due to a reduction in clinical trial drug manufacturing.

*General and Administrative*

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

Increase    % Increase



Edgar Filing: XBiotech Inc. - Form 10-Q

	Three Months Ended March 31,		(Decrease) (Decrease)	
	2018	2017		
Salaries and related expenses	\$324	\$469	\$ (145 )	-31 %
Patent filing expense	181	186	(5 )	-3 %
Stock-based compensation	22	430	(408 )	-95 %
Professional fees	207	415	(208 )	-50 %
Other	423	583	(160 )	-27 %
Total	\$1,157	\$2,083	\$ (926 )	-44 %

General and administrative expense decreased \$0.9 million to \$1.2 million for the three months ended March 31, 2018, compared to \$2.1 million for the three months ended March 31, 2017. The decrease was primarily related to stock-based compensation expenses of \$0.4 million, due to the forfeiture of terminated employees' stock options. Professional fees also decreased \$0.2 million due to the reduction of public relations activities. The decrease in labor costs was mainly due to the reduction of our general and administrative workforce from 10 to 5.

***Other income (loss)***

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

	Three Months Ended March 31, 2018 2017	
Interest income	\$64	\$49
Foreign exchange gain (loss)	17	(341)
Total	\$81	\$(292)

The \$64 thousand of interest income for the three months ended March 31, 2018 is mainly from the interest generated from the Company's Canadian bank account. Foreign exchange gain was mainly due to the fluctuation between US dollar and Euro in the three months ended March 31, 2018 compared to the three months ended March 31, 2017.

## Liquidity and Capital Resources

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

Since our inception on March 22, 2005 through March 31, 2018, we have funded our operations principally through public offerings and the private placement of equity securities, which have provided aggregate cash proceeds of approximately \$257.4 million. The following table summarizes our sources and uses of cash (in thousands):

	Three Months Ended March 31,	
	2018	2017
Net cash (used in) provided by:		
Operating activities	\$(3,526)	\$(11,908)
Investing activities	(34 )	(607 )
Financing activities	201	32,713
Effect of foreign exchange rate on cash and cash equivalents	7	110
Net change in cash and cash equivalents	\$(3,352)	\$20,308

During the three months ended March 31, 2018 and 2017, our operating activities used net cash of \$3.5 million and \$11.9 million, respectively. The use of net cash in each of these periods primarily resulted from our net losses. The decrease in net loss from operations for the three months ended March 31, 2018 as compared to the three months ended March 31, 2017 was mainly due to the decrease in clinical trials and sponsored research expense and salaries and related expenses.

During the three months ended March 31, 2018 and 2017, our investing activities used net cash of \$34 thousand and \$607 thousand, respectively. The use of cash was for the purchase of new research and development equipment.

During the three months ended March 31, 2018 and 2017, our financing activities provided net cash proceeds of \$0.2 million and \$32.7 million, respectively. During the three months ended March 31, 2018, employees exercised stock options to purchase a total of 80,500 shares of our common stock for approximately \$0.2 million in net proceeds. During the three months ended March 31, 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 66 thousand shares of common stock for a total of approximately \$0.3 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 EMA or similar regulatory agencies in other countries and successfully commercialized. As of March 31, 2018, our principal sources of liquidity were our cash and cash equivalents, which totaled approximately \$28.4 million.

**Contractual Obligations and Commitments**

On January 12, 2008, we entered a lease agreement to lease our office space in Austin, Texas. On September 15, 2010, we entered into a second lease agreement to lease additional space in Austin, Texas. On March 20, 2013, we extended the lease for an additional 21 months on the same terms and rental rates as the current lease. On February 28, 2015, we extended the lease for another 4 years. The future minimum lease payments are as follows as of March 31, 2018 (in thousands):

Contractual Obligations	Total	Less than 1 Year	1 - 3 Years	More than 3 years
Operating facility leases	\$433	\$433	\$ —	\$ —
Total contractual obligations	\$433	\$433	\$ —	\$ —

Rent expense was \$200 thousand and \$186 thousand for the three months ended March 31, 2018 and 2017, 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 first quarter of the year ended December 31, 2018 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.

The plaintiffs re-filed their suit in Travis County district court, located in Austin, Texas, on July 6, 2017. XBiotech subsequently removed the case to the U.S. District Court for the Western District of Texas. Following a recent Supreme Court decision holding that the types of claims asserted in this action are non-removable, the suit was remanded back to Travis County district court, where it remains pending. XBiotech believes the claims asserted in the case are without merit and intends to mount a vigorous defense.

### **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, 2017. 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, 2017, 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 March 31, 2018, formatted in Extensive Business Reporting Language (XBRL): (i) condensed consolidated balance sheets, (ii) condensed consolidated statements of operations, (iii) condensed consolidated statements of comprehensive loss, (iv) condensed consolidated statements of cash flows and (v) notes to condensed consolidated financial statements (detail tagged).

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: May 8, 2018      **XBIOTECH INC.**

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

Date: May 8, 2018 By: /S/ Queena Han  
Queen Han  
Vice President, Finance and Human Resources, and Secretary  
*(Principal Financial Officer and Principal Accounting Officer)*