

**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, 2019

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.)

5217 Winnebago Ln, 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 every Interactive Data File required to be submitted 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 such files). Yes No

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
Non-accelerated filer

Accelerated filer
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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, no par value	XBIT	NASDAQ Global Select Market

As of May 9, 2019, there were 36,113,175 shares of the Registrant's common stock issued and outstanding.

XBIOTECH INC.
THREE MONTHS ENDED MARCH 31, 2019
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CAUTIONARY STATEMENTS REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements, which reflect our current views with respect to, among other things, our operations and financial performance. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q are forward-looking statements. You can identify forward-looking statements by terminology such as “may,” “will,” “should,” “would,” “could,” “expects,” “plans,” “contemplate,” “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 bermekimab 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 bermekimab and other product candidates;
- our ability to advance product candidates into, and successfully complete, clinical trials;
- our ability to successfully commercialize the sale of bermekimab 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 bermekimab 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, 2018 filed with the SEC on March 14, 2019, as amended by Amendment No. 1 filed with the SEC on March 15, 2019, 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, 2019 (unaudited)	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	\$ 12,019	\$ 15,823
Prepaid expenses and other current assets	963	1,193
Total current assets	12,982	17,016
Property and equipment, net	26,842	27,329
Total assets	\$ 39,824	\$ 44,345
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	\$ 1,861	\$ 1,653
Accrued expenses	980	1,291
Total current liabilities	2,841	2,944
Long-term liabilities:		
Deferred rent	-	3
Total liabilities	2,841	2,947
Shareholders' equity:		
Preferred stock, no par value, unlimited shares authorized, no shares outstanding	-	-
Common stock, no par value, unlimited shares authorized, 36,090,125 and 35,899,772 shares outstanding at March 31, 2019 and December 31, 2018, respectively	280,664	279,353
Accumulated other comprehensive loss	(117)	(255)
Accumulated deficit	(243,564)	(237,700)
Total shareholders' equity	36,983	41,398
Total liabilities and shareholders' equity	\$ 39,824	\$ 44,345

See accompanying notes.

XBiotech Inc.
Consolidated Statements of Operations
(in thousands, except share and per share data)

	Three Months Ended March 31,	
	2019	2018
	(unaudited)	(unaudited)
Operating expenses:		
Research and development	\$ 4,527	\$ 2,993
General and administrative	1,278	1,157
Total operating expenses	5,805	4,150
Loss from operations	(5,805)	(4,150)
Other income (loss):		
Interest income	78	64
Other income	9	-
Foreign exchange gain (loss)	(146)	17
Total other income (loss)	(59)	81
Net loss	\$ (5,864)	\$ (4,069)
Net loss per share—basic and diluted	\$ (0.16)	\$ (0.11)
Shares used to compute basic and diluted net loss per share	35,977,422	35,447,304

See accompanying notes.

XBiotech Inc.
Consolidated Statements of Comprehensive Loss
(in thousands)

	Three Months Ended March 31,	
	2019	2018
	(unaudited)	(unaudited)
Net loss	\$ (5,864)	\$ (4,069)
Foreign currency translation adjustment	138	7
Comprehensive loss	<u>\$ (5,726)</u>	<u>\$ (4,062)</u>

See accompanying notes.

XBiotech Inc.
Consolidated Statements of Shareholders' Equity
(in thousands)

	Number of Shares	Common Stock Amount	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total
Balance at December 31, 2018	35,900	\$ 279,353	\$ (255)	\$ (237,700)	\$ 41,398
Net loss	-	-	-	(5,864)	(5,864)
Foreign currency translation adjustment	-	-	138	-	138
Issuance of common stock under stock option plan	190	643	-	-	643
Stock subscription receivable	-	(102)	-	-	(102)
Collection of stock subscription receivable	-	200	-	-	200
Share-based compensation expense	-	570	-	-	570
Balance at March 31, 2019	36,090	\$ 280,664	\$ (117)	\$ (243,564)	\$ 36,983

	Number of Shares	Common Stock Amount	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total
Balance at December 31, 2017	35,439	\$ 277,492	\$ (768)	\$ (216,562)	\$ 60,162
Net loss	-	-	-	(4,069)	(4,069)
Foreign currency translation adjustment	-	-	6	-	6
Issuance of common stock under stock option plan	81	201	-	-	201
Share-based compensation expense	-	110	-	-	110
Balance at March 31, 2018	35,520	\$ 277,803	\$ (762)	\$ (220,631)	\$ 56,410

See accompanying notes.

XBiotech Inc.
Consolidated Statements of Cash Flows
(in thousands)

	Three Months Ended March 31,	
	2019	2018
	(unaudited)	(unaudited)
Operating activities		
Net loss	\$ (5,864)	\$ (4,069)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	602	588
Share-based compensation expense	570	110
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	230	232
Accounts payable	99	(596)
Accrued expenses	(311)	212
Deferred rent	(3)	(3)
Net cash used in operating activities	(4,677)	(3,526)
Investing activities		
Purchase of property and equipment	(6)	(34)
Net cash used in investing activities	(6)	(34)
Financing activities		
Issuance of common stock under stock option plan	541	201
Collection of subscription receivable	200	-
Net cash provided by financing activities	741	201
Effect of foreign exchange rate on cash and cash equivalents	138	7
Net change in cash and cash equivalents	(3,804)	(3,352)
Cash and cash equivalents, beginning of period	15,823	31,768
Cash and cash equivalents, end of period	\$ 12,019	\$ 28,416
Supplemental Information:		
Accrued purchases of property and equipment	109	25
Subscription receivable	102	-

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, 2019 and December 31, 2018, the results of its operations and comprehensive loss for the three month periods ended March 31, 2019 and 2018, and the cash flows for the three month periods ended March 31, 2019 and 2018.

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. These nonrefundable advance payments are recorded within other prepaid expenses and other current assets in the consolidated balance sheets. 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, 2019 and 2018 was included in the following line items on the Consolidated Statements of Operations (in thousands).

	Three Months Ended March 31,	
	2019	2018
Research and development	\$ 295	\$ 88
General and administrative	275	22
Total share-based compensation expense	\$ 570	\$ 110

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,	
	2019	2018
Dividend yield	-	-
Expected volatility	80% - 82%	67% - 80%
Risk-free interest rate	2.46% - 2.64%	2.38% - 2.71%
Expected life (in years)	5.75 - 10	6.0 - 10
Weighted-average grant date fair value per share	\$3.92	\$3.02

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, 2019 and December 31, 2018, 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, 2019 and December 31, 2018, 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, 2019.

Income Taxes

Income taxes are recorded in accordance with ASC 740, Accounting for Income Taxes (“ASC 740”), which provides for deferred taxes using an asset and liability approach. The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. The Company determines its deferred tax assets and liabilities based on differences between financial reporting and tax bases of assets and liabilities, which are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. Valuation allowances are provided if based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

ASC 740 clarifies the accounting for uncertainty in income taxes recognized in the financial statements and provides that a tax benefit from an uncertain tax position may be recognized when it is more likely than not that the position will be sustained upon examination, including resolutions of any related appeals or litigation processes, based on the technical merits. This interpretation also provides guidance on measurement, derecognition, classification, interest and penalties, accounting in interim periods and disclosure. The Company’s policy for recording interest and penalties associated with uncertain tax positions is to record such items as a component of tax expense.

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 established Topic 842, Leases, by issuing Accounting Standards Update (ASU) No. 2016-02, which supersedes ASC 840, Leases, and requires lessees to recognize leases on-balance sheet and disclose key information about leasing arrangements. Topic 842 was subsequently amended by ASU No. 2018-01, Land Easement Practical Expedient for Transition to Topic 842; ASU No. 2018-10, Codification Improvements to Topic 842, Leases; and ASU No. 2018-11, Targeted Improvements. Topic 842, as amended (the "new lease standard") establishes a right-of-use model (ROU) that requires a lessee to recognize a ROU asset and lease liability on the balance sheet for all leases with a term longer than 12 months. Leases will be classified as finance or operating, with classification affecting the pattern and classification of expense recognition in the income statement. The effective date of the new guidance is for the Company's first quarter of fiscal year 2019. The FASB has approved an optional, alternative method to adopt the lease standard by recognizing a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. The Company adopted the new standard effective January 1, 2019, using the alternative method. The Company does not have a cumulative adjustment impacting retained earnings. Adoption of the lease standard does not have a material impact on the Company's consolidated financial statements.

3. Property and Equipment

Property and equipment consisted of the following as of December 31, 2019 and 2018 (in thousands):

	March 31, 2019	December 31, 2018
Manufacturing equipment	\$ 4,567	\$ 4,937
Winnebago building	19,810	19,945
Other fixed assets	2,465	2,447
Total property and equipment	<u>\$ 26,842</u>	<u>\$ 27,329</u>

4. 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 2018, 161 thousand shares of common stock were issued upon the exercise of stock options at a price of \$2.50 per share for a total of \$401 thousand, of which \$200 thousand is subscription receivable.

From January through March 2019, 190 thousand shares of common stock were issued upon the exercise of stock options at a price of \$2.5 to \$10.00 per share for a total of \$643 thousand.

5. 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, 2018	5,535,439	\$2.5	-	\$21.99	7.30
Granted	215,000	5.15	-	9.84	5.60
Exercised	(190,903)	2.5	-	10	3.38
Forfeitures	(126,875)	2.5	-	14.18	8.06
Options outstanding at March 31, 2019	5,432,661	\$2.5	-	\$21.99	7.36

As of March 31, 2019, there was approximately \$3.2 million of unrecognized compensation cost, related to stock options granted under the Plans which will be amortized to stock compensation expense over the next 2.02 years.

6. Subsequent Events

On April 30, 2019, the Company entered into an Equity Distribution Agreement with Piper Jaffray & Co which establishes an at-the-market equity program. The Sales Agreement provides for the sale of up to 4,334,453 shares of our Common Stock (for details see Form 424B5 filed April 30, 2019).

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, 2019, we had an accumulated deficit of \$243.6 million. We had net losses of \$5.8 million and \$4.1 million for the three months ended March 31, 2019 and 2018, 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, 2019, we had 56 employees.

Recent Events:

The Company has recently completed two open label, multi center phase 2 clinical studies evaluating bermekimab as a treatment for atopic dermatitis and hidradenitis suppurativa. The Company announced positive findings from these studies, both of which were presented at the American Academy of Dermatology's Annual Meeting in March 2019. XBiotech plans to continue its pursuit of the development of its clinical pipeline along with research and development efforts to enable selection of drug candidates and research projects for further development in response to their preclinical and clinical success and commercial potential.

Risks

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 \$12.0 million at March 31, 2019 will enable the Company to achieve some key inflection points, including 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, 2019 will enable us to fund our operating expenses and capital expenditure requirements through March 31, 2020. We have based this estimate on assumptions that may prove to be inaccurate, 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, bermekimab, 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, 2019, we have recorded total research and development expenses, including share-based compensation, of \$190.2 million. Our total research and development expenses for the three months ended March 31, 2019 and 2018 were \$4.5 million and \$3.0 million, respectively. Share-based compensation accounted for \$295 thousand and \$100 thousand for the three months ended March 31, 2019 and 2018, respectively.

Research and development expenses, as a percentage of total operating expenses for the three months ended March 31, 2019 and 2018 were 78% and 72%, respectively. The percentages, excluding stock-based compensation, for the three months ended March 31, 2019 and 2018, were 81% and 72%, respectively.

The clinical development costs may further increase going forward with potentially more advanced studies in the future as we evaluate our clinical data and pipeline.

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, 2019 and 2018 were \$1.3 million and \$1.2 million, respectively. Share-based compensation accounted for \$275 thousand and \$22 thousand for the three months ended March 31, 2019 and 2018, respectively.

General and administrative expense, as a percentage of total operating expenses for the three months ended March 31, 2019 and 2018 were 22% and 28%, respectively. The percentages, excluding stock-based compensation, for the three months ended March 31, 2019 and 2018, were 19% and 28%, 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, 2018.

Results of Operations

Revenue

We did not record any revenue during the three months ended March 31, 2019 and 2018.

Expenses

Research and Development

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

	Three Months Ended March 31,		Increase	% Increase
	2019	2018	(Decrease)	(Decrease)
Salaries and related expenses	\$ 1,166	\$ 1,051	\$ 115	11%
Laboratory and manufacturing supplies	1,242	213	1,029	483%
Clinical trials and sponsored research	256	8	248	3100%
Stock-based compensation	295	88	207	235%
Other	1,568	1,633	(65)	-4%
Total	\$ 4,527	\$ 2,993	\$ 1,534	51%

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

Research and development expenses increased \$1.5 million to \$4.5 million for the three months ended March 31, 2019, compared to \$3.0 million for the three months ended March 31, 2018. The increase was mainly due to a \$1.0 million increase of laboratory and manufacturing supplies, related to the clinical drug manufacturing. In addition, there was an increase in clinical trials and sponsored research due to the active trials started in 2018. Stock-based compensation also increased due to the new grants to employees in 2018 and 2019.

General and Administrative

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

	Three Months Ended March 31,		Increase	% Increase
	2019	2018	(Decrease)	(Decrease)
Salaries and related expenses	\$ 254	\$ 324	\$ (70)	-22%
Patent filing expense	199	181	18	10%
Stock-based compensation	275	22	253	1150%
Professional fees	184	207	(23)	-11%
Other	366	423	(57)	-13%
Total	\$ 1,278	\$ 1,157	\$ 121	10%

General and administrative expense increased \$0.1 million to \$1.3 million for the three months ended March 31, 2019, compared to \$1.2 million for the three months ended March 31, 2018. The increase was primarily related to stock-based compensation expenses of \$0.3 million, due to the new grants to employees in 2018 and 2019. We had offsetting decreases in Salaries and related expense and facility allocation expense in other expense, due to one employee transferred from general and administrative to research and development.

Other income (loss)

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

	Three Months Ended March 31,	
	2019	2018
Interest income	\$ 78	\$ 64
Other income	9	-
Foreign exchange gain (loss)	(146)	17
Total	<u>\$ (59)</u>	<u>\$ 81</u>

The interest income for the three months ended March 31, 2019 and 2018 was mainly from the interest generated from the Company's Canadian bank account. Foreign exchange gain and loss was mainly due to the fluctuation between US dollar and Euro in the three months ended March 31, 2019 compared to the three months ended March 31, 2018.

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, 2019, we have funded our operations principally through public offerings and the private placement of equity securities, which have provided aggregate cash proceeds of approximately \$258.1 million. The following table summarizes our sources and uses of cash (in thousands):

	Three Months Ended March 31,	
	2019	2018
Net cash (used in) provided by:		
Operating activities	\$ (4,677)	\$ (3,526)
Investing activities	(6)	(34)
Financing activities	741	201
Effect of foreign exchange rate on cash and cash equivalents	138	7
Net change in cash and cash equivalents	<u>\$ (3,804)</u>	<u>\$ (3,352)</u>

During the three months ended March 31, 2019 and 2018, our operating activities used net cash of \$4.7 million and \$3.5 million, respectively. The use of net cash in each of these periods primarily resulted from our net losses. The increase in net loss from operations for the three months ended March 31, 2019 as compared to the three months ended March 31, 2018 was mainly due to the increase in laboratory and manufacturing supplies.

During the three months ended March 31, 2019 and 2018, our investing activities used net cash of \$6 thousand and \$34 thousand, respectively. The use of cash was for the purchase of new research and development equipment.

During the three months ended March 31, 2019 and 2018, our financing activities provided net cash proceeds of \$0.7 million and \$0.2 million, respectively. During the three months ended March 31, 2019, employees exercised stock options to purchase a total of 190 thousand shares of our common stock for approximately \$0.5 million in net proceeds. In this period, the Company also collected \$0.2 million of its subscription receivable balance. During the three months ended March 31, 2018, employees exercised stock options to purchase a total of 81 thousand shares of our common stock for approximately \$0.2 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 FDA, EMA or similar regulatory agencies in other countries and successfully commercialized. As of March 31, 2019, our principal sources of liquidity were our cash and cash equivalents, which totaled approximately \$12.0 million.

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, 2019 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. 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, 2018. 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, 2018, which could materially affect our business, financial condition or future results. The risks described in our Annual Report on Form 10-K, as well as other risks and uncertainties, could materially and adversely affect our business, results of operations and financial condition, which in turn could materially and adversely affect the trading price of shares of our Common Stock. Additional risks not currently known or currently material to us may also harm our business.

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

Not Applicable.

Item 3. Defaults upon Senior Securities

Not Applicable.

Item 4. Mine Safety Disclosures

Not Applicable.

Item 5. Other Information.

Not Applicable.

Item 6. Exhibits.

[31.1](#) [Certification of Principal Executive Officer Required Under Rule 13a-14\(a\) and 15d-14\(a\) of the Securities Exchange Act of 1934, as amended.](#)

[31.2](#) [Certification of Principal Financial Officer Required Under Rule 13a-14\(a\) and 15d-14\(a\) of the Securities Exchange Act of 1934, as amended.](#)

[32.1](#) [Certification of Principal Executive Officer and Principal Financial Officer Required Under Rule 13a-14\(b\) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. §1350.](#)

101 The following financial statements from the XBiotech Inc. Quarterly Report on Form 10-Q for the quarter ended March 31, 2019, 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 shareholders' equity; (v) condensed consolidated statements of cash flows and (vi) 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 9, 2019

XBIOTECH INC.

By: /S/ John Simard

John Simard
President, Chief Executive Officer and Director
(Principal Executive Officer)

Date: May 9, 2019

By: /S/ Queena Han

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

CERTIFICATIONS

I, John Simard, certify that:

1. I have reviewed this quarterly report on Form 10-Q of XBiotech Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 9, 2019

/S/ John Simard

John Simard

Chief Executive Officer and President
(Principal Executive Officer)

CERTIFICATIONS

I, Queena Han, certify that:

1. I have reviewed this quarterly report on Form 10-Q of XBiotech Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 9, 2019

/S/ QUEENA HAN

Queena Han

Vice President, Finance and Human Resources and Secretary
(Principal Financial Officer)

**CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL
OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of XBiotech Inc. on Form 10-Q for the period ended March 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, John Simard, Chief Executive Officer and President of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of XBiotech Inc.

/S/ JOHN SIMARD

John Simard
Chief Executive Officer and President
(Principal Executive Officer)
Date: May 9, 2019

In connection with the Quarterly Report of XBiotech Inc. on Form 10-Q for the period ended March 31, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Queena Han, Vice President of Finance, Human Resources and Secretary of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of XBiotech Inc.

/S/ QUEENA HAN

Queenana Han
Vice President, Finance and Human Resources and
Secretary
(Principal Financial Officer)
Date: May 9, 2019
