

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended **June 30, 2020**

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)

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

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, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input checked="" type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of August 10, 2020, there were 28,989,172 shares of the Registrant's common stock issued and outstanding.

XBIOTECH INC.
THREE MONTHS AND SIX MONTHS ENDED JUNE 30, 2020
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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:

- *potential impacts due to the coronavirus pandemic such as delays, interruptions or other adverse effects to clinical trials, delays in manufacturing and supply chain interruptions, and the overall impact of the coronavirus pandemic on our business, financial condition and results of operations;*
- *our ability to obtain regulatory approval to market and sell our product candidates 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 our product candidates;*
- *our ability to advance product candidates into, and successfully complete, clinical trials;*
- *our ability to successfully commercialize the sale of our product candidates 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 meet our drug manufacturing and clinical trial management obligations under our contractual arrangements with Janssen;*
- *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;

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- 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 our 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, foreign currency fluctuations and regional or global economic impacts caused by public health threats, such as the outbreak of coronavirus or other infectious diseases;
- 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, 2019 filed with the SEC on March 16, 2020, and under the heading "Risk Factors" 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.

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XBiotech Inc.

Consolidated Balance Sheets
(in thousands, except share data)

	June 30, 2020	December 31,
	(unaudited)	2019
Assets		
Current assets:		
Cash and cash equivalents	\$ 229,703	\$ 714,594
Accounts receivable	20,679	-
Deferred cost of goods sold	2,230	-
Income tax receivable	4,975	-
Prepaid expenses and other current assets	802	1,669
Total current assets	258,389	716,263
Property and equipment, net	24,882	25,171
Escrow receivable	75,048	75,000
Deferred tax asset	443	443
Total assets	\$ 358,762	\$ 816,877
Liabilities and shareholders' equity		

Current liabilities:			
Accounts payable		\$ 5,240	\$ 2,149
Accrued expenses		4,831	4,180
Deferred revenue		1,500	-
Contract liabilities		-	4,500
Income taxes payable		2,565	49,361
Total current liabilities		14,136	60,190
Long-term liabilities:			
Income tax payable - non-current		1,056	1,056
Total liabilities		15,192	61,246
Shareholders' equity:			
Preferred stock, no par value, unlimited shares authorized, no shares outstanding		-	-
Common stock, no par value, unlimited shares authorized, 28,897,394 and 41,519,633 shares outstanding at June 30, 2020 and December 31, 2019, respectively		246,395	324,808
Accumulated other comprehensive loss		(137)	(106)
Retained earnings		97,312	430,929
Total shareholders' equity		343,570	755,631
Total liabilities and shareholders' equity		\$ 358,762	\$ 816,877

See accompanying notes.

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XBiotech Inc.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
	(unaudited)	(unaudited)	(unaudited)	(unaudited)
Revenue				
Manufacturing revenue	\$ 4,500	\$ -	\$ 7,500	\$ -
Clinical trial service revenue	10,998	-	20,679	-
Total revenue	15,498	-	28,179	-
Cost of goods sold				
Manufacturing cost	3,956	-	6,122	-
Clinical trial cost	9,245	-	16,753	-
Total cost of goods sold	13,201	-	22,875	-
Gross margin	2,297	-	5,304	-
Operating expenses:				
Research and development	2,565	4,693	3,720	\$ 9,220
General and administrative	6,246	1,313	10,269	2,591
Total operating expenses	8,811	6,006	13,989	11,811
Loss from operations	(6,514)	(6,006)	(8,685)	(11,811)
Other income (loss):				
Interest income	306	51	2,204	129
Other income (loss)	(503)	1	(503)	10
Foreign exchange gain (loss)	(465)	102	(558)	(44)
Total other income (loss)	(662)	154	1,143	95
Loss before income taxes	(7,176)	(5,852)	(7,542)	(11,716)
Benefit for income taxes	(332)	-	(684)	-
Net loss	\$ (6,844)	\$ (5,852)	\$ (6,858)	\$ (11,716)
Net loss per share—basic and diluted	\$ (0.24)	\$ (0.16)	\$ (0.21)	\$ (0.32)
Shares used to compute basic net loss per share	28,856,085	37,519,697	32,512,789	36,752,820

See accompanying notes.

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XBiotech Inc.

Consolidated Statements of Comprehensive Loss
(in thousands)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020 (unaudited)	2019 (unaudited)	2020 (unaudited)	2019 (unaudited)
Net loss	\$ (6,844)	\$ (5,852)	\$ (6,858)	\$ (11,716)
Foreign currency translation adjustment	(121)	(99)	(31)	39
Comprehensive loss	<u>\$ (6,965)</u>	<u>\$ (5,951)</u>	<u>\$ (6,889)</u>	<u>\$ (11,677)</u>

See accompanying notes.

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XBiotech Inc.

Consolidated Statements of Shareholders' Equity
(in thousands)

	Number of Shares	Common Stock Amount	Accumulated Other		Total
			Comprehensive Income (Loss)	Accumulated Deficit	
Balance at March 31, 2020	28,853	\$ 242,942	\$ (16)	\$ 104,156	\$ 347,082
Net loss	-	-	-	(6,844)	(6,844)
Foreign currency translation adjustment	-	-	(121)	-	(121)
Issuance of common stock under stock option plan	44	339	-	-	339
Stock subscription receivable	-	(62)	-	-	(62)
Share-based compensation expense	-	3,176	-	-	3,176
Balance at June 30, 2020	<u>28,897</u>	<u>246,395</u>	<u>(137)</u>	<u>97,312</u>	<u>343,570</u>

	Number of Shares	Common Stock Amount	Accumulated Other		Total
			Comprehensive Income (Loss)	Accumulated Deficit	
Balance at March 31, 2019	36,090	\$ 280,664	\$ (117)	\$ (243,564)	\$ 36,983
Net loss	-	-	-	(5,852)	(5,852)
Foreign currency translation adjustment	-	-	(99)	-	(99)
Issuance of common stock offering, net of issuance cost	4,848	37,497	-	-	37,497
Issuance of common stock under stock option plan	65	296	-	-	296
Collection of stock subscription receivable	-	102	-	-	102
Share-based compensation expense	-	486	-	-	486
Balance at June 30, 2019	<u>41,003</u>	<u>319,045</u>	<u>(216)</u>	<u>(249,416)</u>	<u>69,413</u>

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	Number of Shares	Common Stock Amount	Accumulated Other		Total
			Comprehensive Income (Loss)	Accumulated Deficit	
Balance at December 31, 2019	41,519	324,808	(106)	430,929	755,631
Net loss	-	-	-	(6,858)	(6,858)
Tender Offer	(14,000)	(93,240)	-	(326,760)	(420,000)

Foreign currency translation adjustment	-	-	(31)	-	(31)
Issuance of common stock under stock option plan	1,378	8,258	-	-	8,258
Collection of stock subscription receivable	-	(62)	-	-	(62)
Share-based compensation expense	-	6,631	-	-	6,631
Balance at June 30, 2020	<u>28,897</u>	<u>246,395</u>	<u>(137)</u>	<u>97,312</u>	<u>343,570</u>

	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	-	-	-	(11,716)	(11,716)
Foreign currency translation adjustment	-	-	39	-	39
Issuance of common stock offering, net of issuance cost	4,848	37,497	-	-	37,497
Issuance of common stock under stock option plan	255	837	-	-	837
Collection of stock subscription receivable	-	302	-	-	302
Share-based compensation expense	-	1,056	-	-	1,056
Balance at June 30, 2019	<u>41,003</u>	<u>319,045</u>	<u>(216)</u>	<u>(249,416)</u>	<u>\$ 69,413</u>

See accompanying notes.

XBiotech Inc.

Consolidated Statements of Cash Flows
(IN THOUSANDS)

	Six Months Ended June 30,	
	2020 (unaudited)	2019 (unaudited)
Operating activities		
Net loss	\$ (6,858)	\$ (11,716)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	1,104	1,199
Share-based compensation expense	6,631	1,056
Deferred cost of goods sold	(2,230)	-
Changes in operating assets and liabilities:		
Account receivable	(20,679)	-
Income tax receivable	(4,975)	-
Escrow receivable	(48)	-
Prepaid expenses and other current assets	868	515
Accounts payable	3,091	(212)
Accrued expenses	651	(379)
Contract liabilities	(4,500)	-
Deferred Revenue	1,500	-
Deferred rent	-	(3)
Tax payable	(46,796)	-
Net cash used in operating activities	<u>(72,241)</u>	<u>(9,540)</u>
Investing activities		
Purchase of property and equipment	(815)	(37)
Net cash used in investing activities	<u>(815)</u>	<u>(37)</u>
Financing activities		
Share repurchases of common stock and warrants, net	(420,000)	37,497
Issuance of common stock under stock option plan	8,258	837
Subscription receivable	(62)	-
Collection of subscription receivable	-	302
Net cash provided by (used in) financing activities	(411,804)	38,636
Effect of foreign exchange rate on cash and cash equivalents	(31)	39
Net change in cash and cash equivalents	(484,891)	29,098
Cash and cash equivalents, beginning of period	714,594	15,823

Supplemental Information:

Accrued purchases of property and equipment	-	109
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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 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.

Since its inception, XBiotech has focused on advancing technology to rapidly identify and clone antibodies from individuals that have resistance to certain diseases and in turn create safe and effective therapies to treat these diseases. At the heart of the Company is a proprietary technical knowhow to translate natural human immunity into therapeutic product candidates. Additionally, the Company has built a framework for commercial manufacturing, using technology that required less capital, fewer operators and provided greater flexibility than standard industry practices.

Currently, the Company is developing new antibodies to replace a previous generation True Human anti-IL-1 α antibody that was sold in 2019. Under terms of the sale, XBiotech is permitted to pursue discovery of new True Human anti-IL-1 α antibodies for use in all areas of medicine with the exception of dermatology.

XBiotech's scientists have discovered and characterized a panel of new anti-IL-1 α antibodies from a human donor and has cloned the genes for these antibodies into cells that can be used for production of novel therapeutics. The antibody products are planned to be used in human clinical trials in 2021 and ultimately commercialized. The Company's Research and Development team has successfully engineered a cell-based production system for the first of its new anti-IL-1 α antibodies to enable the Company's drug manufacturing process at its state-of-the-art facility in Austin, Texas, for which the Company has broken ground on an expansion project to accommodate future growth. The new antibody targets damaging inflammation by neutralizing interleukin-1alpha (IL-1 α), an inflammatory substance produced by the body, which is involved in diseases such as cancer, arthritis and cardiovascular indications. With the right to pursue the discovery and development of new True HumanTM antibodies targeting IL-1 α outside of dermatology, this product candidate is the first in a line of new therapies being developed at XBiotech which are planned to be pursued in major areas of medicine with unmet need.

The Company has developed and transferred screening technology to a blood donor organization that enables blood donors that have COVID-19 immunity to be identified. XBiotech scientists have been searching for ideal blood donors with strong natural immunity to COVID-19. During the second quarter XBiotech has identified and selected convalescent donors to support the Company's development of a novel True Human antibody therapy for COVID-19. The Company has subsequently started antibody discovery from the blood cells of these select donors and is currently in the process of identifying lead antibody candidates. The Company hopes to quickly proceed to cell line development as soon as these leads are identified.

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. All of these risks are likely to be exacerbated by the outbreak of the novel strain of coronavirus, SARS-CoV-2 ("COVID-19") and its ongoing impact, which has disrupted our business operations and will continue to do so. We cannot determine at this time the length or severity of these disruptions. The Company's ability to fund its planned clinical operations, including completion of its planned trials, is expected to depend on the amount and timing of cash receipts from future collaboration or product sales and/or financing transactions. On December 30, 2019, the Company entered into a clinical manufacturing agreement and a clinical trial service agreement with Janssen Biotech Inc. The Company believes that its cash and cash equivalents of \$229.7 million at June 30, 2020, as well as revenue generated from the Janssen contracts will enable the Company to achieve several major inflection points, including potential new clinical studies with our lead product candidate. We expect to have sufficient cash through one year from the report issuance date.

2. Significant Accounting Policies

Basis of Presentation

These consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States (“US GAAP”). In the opinion of management, the accompanying consolidated financial statements reflect all adjustments (consisting only of normal recurring items) considered necessary to present fairly the Company’s financial position at June 30, 2020 and December 31, 2019, the results of its operations and comprehensive loss for the three months and six months periods ended June 30, 2020 and 2019, and the cash flows for the six months periods ended June 30, 2020 and 2019.

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.

Revenue

Revenue from Janssen Agreements

The Company recognizes revenues from its Janssen Agreements as follows.

The Company entered into its clinical manufacturing and clinical trial services arrangements in connection with its sale of certain intellectual property on December 30, 2019. These contracts commenced January 1, 2020. While these agreements are not considered contracts with a customer based on the terms thereof, we are applying the revenue recognition guidance by analogy.

XBiotech is still in the research and development phase; however, the eventual output of the Company’s intended ordinary activities will be the licensing of intellectual property and/or sale of commercialized compounds for use in pharmaceutical treatment of disease, not the performance of manufacturing of development stage compounds or clinical trials for others. Although Janssen is not a customer, as these services are not the output of XBiotech’s ordinary activities, the Company evaluated the terms of the agreements and has analogized to Accounting Standards Codification, Topic 606, *Revenue from Contracts with Customers* (“ASC 606”) for clinical manufacturing and clinical trial services revenue recognition.

Under ASC 606, an entity recognizes revenue when (or as) its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606 (or for those analogized to it), the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. We only apply the five-step model to contracts (including by analogy) when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer to the counterparty. At contract inception, once the contract is determined to be within the scope of or analogized to ASC 606, we assess the goods or services promised within each contract and determine those that are performance obligations, and assess whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Manufacturing Revenue

We have a Clinical Manufacturing Agreement that we account for by analogy to ASC 606, under which we agreed to manufacture bermekimab for use by Janssen in clinical trials, in exchange for payments of \$4.5 million per quarter, paid in advance, for up to two years, though Janssen may terminate the contract for any reason with 60-days' notice. Quantities are estimated for the two-year period, but are only binding on the Company and Janssen for the next four months of each period, other than by the 60-day notice termination. If, during any calendar quarter, the Company fails to deliver all of the Clinical Products ordered by Janssen, subject to our agreed upon capacity, the next quarter's fee is reduced proportionately for the shortfall volume. Negative adjustments may also occur for delivered Clinical Products that do not meet quality specifications, though we expect to meet these standards.

We received payment of \$4.5 million from Janssen based on billing schedules established in the contract on December 30, 2019 for manufacturing in the first quarter of 2020. Due to the coronavirus pandemic, the Company failed to fully complete the manufacture of drugs specified for the March purchase order due to supply disruptions for the syringes used to hold the manufactured compound. We completed the manufacturing for this order in the second quarter of 2020. In addition, due to the pandemic, Janssen requested that we delay shipment of volumes for which we had completed manufacturing. We recognized revenue for those volumes held at Janssen's request, as they are segregated for future delivery. As of June 30, 2020, the Company had not completed the manufacture of drugs specified for the June purchase order due to additional syringe supply disruptions. We received the syringe shipment in June, and currently anticipate fulfilling all production volumes and returning to normal manufacturing capabilities in the third quarter of 2020; however, due to the uncertainty associated with the pandemic and related mitigation efforts, it is possible this assessment could change in future periods.

Clinical Trial Service Revenue

On December 30, 2019, we entered into a Transition Services Agreement with Janssen. Pursuant to the Transition Services Agreement, the Company has agreed to continue operational management, on a fee-for-service basis, of two ongoing clinical trials related to bermekimab. The arrangement may continue as long as the clinical trials are ongoing; however, Janssen may terminate the contract at any time with 30 day notice.

The coronavirus pandemic had no material effect on our clinical trial services during the second quarter of 2020. However, the timelines for future clinical trial services could be extended in the future as a result of the pandemic, which could delay or otherwise adversely affect our revenue. Because our fees are directly related to third party costs of our vendors, our clinical trial service revenues in future periods are likely to be affected by our vendors' ability to operate and the activities of trial candidates due to the effects of the pandemic and mitigating activities. Our first and second quarter results may not be indicative of future revenues or costs associated with these clinical trials.

There was no material affect to our clinical trial services by the coronavirus pandemic during the second quarter of 2020. However, the timelines for future clinical trial services could be extended in the future as a result of the pandemic, which could delay or otherwise adversely affect our revenue. Because our fees are directly related to third party costs of our vendors, our clinical trial service revenues in future periods are likely to be affected by our vendors' ability to operate and the activities of trial candidates due to the effects of the pandemic and mitigating activities. Our second quarter results may not be indicative of future revenues or costs associated with these clinical trials.

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.

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 and six months ended June 30, 2020 and 2019 was included in the following line items on the Consolidated Statements of Operations (in thousands).

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Research and development	\$ 1,214	\$ 291	\$ 1,747	\$ 586
General and administrative	1,872	195	4,016	470
Cost of goods sold	89	-	868	-
Total share-based compensation expense	<u>\$ 3,175</u>	<u>\$ 486</u>	<u>\$ 6,631</u>	<u>\$ 1,056</u>

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

	Three Months Ended June 30,				Six Months Ended June 30,			
	2020		2019		2020		2019	
Dividend yield	-	-	-	-	-	-	-	-
Expected volatility	88%	91%	88%	91%	88%	91%	80%	91%
Risk-free interest rate	0.43%	0.47%	1.80%	2.35%	0.42%	1.87%	1.80%	2.64%
Expected life (in years)	6.25	5.75	6.25	6.25	10	5.75	-	10
Weighted-average grant date fair value per share	14.02	5.56	14.88	4.99				

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 consolidated financial statements include financial instruments for which the fair market value of such instruments may differ from amounts reflected on a historical cost basis. Financial instruments of the Company consist of cash deposits, accounts and other receivables, accounts payable, and certain accrued liabilities. These financial instruments are held at cost, which generally approximates fair value due to their short-term nature.

The Company follows ASC Topic 820, *Fair Value Measurements and Disclosures*, which establishes a fair value hierarchy for those instruments measured at fair value that distinguishes between assumptions based on market data (observable inputs) and the Company's own assumptions (unobservable inputs). The hierarchy consists of three levels:

- Level 1—Unadjusted quoted prices in active markets for identical assets or liabilities.
- Level 2—Quoted prices for similar assets and liabilities in active markets, quoted prices in markets that are not active, or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liability.
- Level 3—Unobservable inputs that reflect the Company's own assumptions about the assumptions market participants would use in pricing the asset or liability in which there is little, if any, market activity for the asset or liability at the measurement date.

At June 30, 2020 and December 31, 2019, the Company did not have any assets or liabilities that are measured at fair value on a recurring basis. The carrying amounts reflected in the balance sheets for cash and cash equivalents, prepaid expenses and other current assets, accounts payable, and accrued expenses approximate their fair values at June 30, 2020 and December 31, 2019, 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
• Mobile facility	27.5 years
• Building	39 years

Costs of major additions and betterments are capitalized; maintenance and repairs, which do not improve or extend the life of the respective assets, are charged to expense as incurred. Upon retirement or sale, the cost of the disposed asset and the related accumulated depreciation are removed from the accounts and the resulting gain or loss is recognized.

Impairment of Long-Lived Assets

The Company periodically evaluates its long-lived assets for potential impairment in accordance with ASC Topic 360, *Property, Plant and Equipment*. Potential impairment is assessed when there is evidence that events or changes in circumstances indicate that the carrying amount of an asset may not be recovered. Recoverability of these assets is assessed based on undiscounted expected future cash flows from the assets, considering a number of factors, including past operating results, budgets and economic projections, market trends and product development cycles. If impairments are identified, assets are written down to their estimated fair value. The Company has not recognized any impairment through June 30, 2020.

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.

The Company makes estimates and judgments in determining the need for a valuation allowance, including the estimation of its taxable income or loss for the three months and six months ended June 30, 2020. Realization of 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 certain deferred tax assets with a valuation allowance. The Company may in the future determine that certain deferred tax assets are more-likely-than-not 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.

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 income/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 income/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 June 2016, the FASB issued guidance on financial instruments and related credit losses. The guidance requires that financial assets measured at amortized cost be presented at the net amount expected to be collected. The allowance for credit losses is a valuation account that is deducted from the amortized cost basis. The statement of comprehensive income reflects the measurement of credit losses for newly recognized financial assets, as well as the expected credit losses during the period. The measurement of expected credit losses is based upon historical experience, current conditions, and reasonable and supportable forecasts that affect the collectability of the reported amount. Credit losses relating to available-for-sale debt securities will be recorded through an allowance for credit losses rather than as a direct write-down to the security. The updated guidance is effective for annual periods beginning after December 15, 2019, and is applicable to the Company in fiscal 2020. The Company adopted the new standard effective January 1, 2020. The primary impact for the Company was the timing of recording expected credit losses on its trade receivables. The Company does not have a history of significant credit losses and this guidance did not have a material impact on its consolidated financial statements.

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. 201801, Land Easement Practical Expedient for Transition to Topic 842; ASU No. 2018-10, Codification Improvements to Topic 842, Leases; and ASU No. 201811, 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 did not have a cumulative adjustment impacting retained earnings. Adoption of the lease standard did not have a material impact on the Company's consolidated financial statements.

In December 2019, the FASB issued ASU 2019-12, Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes, which simplifies the accounting for income taxes by removing certain exceptions to the general principles in Topic 740. The amendments also improve consistent application of and simplify GAAP for other areas of Topic 740 by clarifying and amending existing guidance. The standard will become effective for interim and annual periods beginning after December 15, 2020, with early adoption permitted. We early adopted ASU 2019-12 during the quarter ended March 31, 2020. The adoption of ASU 2019-12 resulted in no material impact to the Company's financial statements.

3. Revenue

We received payment of \$4.5 million for the second quarter of 2020 from Janssen in June 2020 based on billing schedules established in the contract on December 30, 2019 for manufacturing. Due to the coronavirus pandemic, the Company did not fully complete the manufacture of drugs specified for the March purchase order until the second quarter, and, as of June 30, 2020, the Company had not completed the manufacture of drugs specified for the June purchase order due to supply disruptions for the syringes used to hold the manufactured compound. In addition, due to the pandemic, Janssen requested that we delay shipment of volumes for which we had completed manufacturing. We recognized revenue for those volumes held at Janssen's request, as they are segregated for future delivery. Consequently, as of June 30, 2020, \$1.5 million has been recorded as deferred revenue to a future period for the volumes that were not completed due to the syringe shortage until they are completed and delivered. We received the syringe shipment in June, and currently anticipate fulfilling all production volumes and returning to normal manufacturing capabilities in the third quarter of 2020; however, due to the uncertainty associated with the pandemic and related mitigation efforts, it is possible this assessment could change in future periods.

On December 30, 2019, the Company entered into a Transition Services Agreement with Janssen. Pursuant to the Transition Services Agreement, the Company has agreed to continue operational management, on a fee-for-service basis, of two ongoing clinical trials related to bermekimab. In consideration for all of the services to be provided, for each calendar quarter during the term of such agreement, Janssen shall pay the Company a fee for such quarter equal to all pass-through costs incurred by the Company during such calendar quarter, exclusive of the allocation of certain internal costs that are not considered pass-through pursuant to the agreement, plus a markup of 30%. For the three months and six months ended June 30, 2020, the Company has recorded \$11.0 and \$20.7 million of gross revenue under this arrangement with the corresponding expense to clinical services cost of goods sold.

4. Property and Equipment

Property and equipment consisted of the following as of June 30, 2020 and December 31, 2019 (in thousands):

	June 30, 2020	December 31, 2019
Manufacturing equipment	\$ 3,156	\$ 3,492
Winnebago building	19,146	19,406
Other fixed assets	2,580	2,273
Total property and equipment	<u>\$ 24,882</u>	<u>\$ 25,171</u>

5. Common Stock

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

During June 2019, under the Common Shares Purchase Agreement with Piper Jaffray & Co., the Company sold 4.8 million shares of common stock at a price \$8.25 per share for total net proceeds of \$37.5 million, including the capitalized underwriter's commission of \$2.3 million and other related fees of \$0.2 million.

From January through December 2019, 771 thousand shares of common stock were issued upon the exercise of stock options at a price of \$2.50 to \$15.00 per share for total proceeds of \$3.8 million.

On January 4, 2020, XBiotech announced that it had commenced a "modified Dutch auction" tender offer to purchase up to \$420.0 million of its common shares, or such lesser number of common shares as are properly tendered and not properly withdrawn, at a price not less than \$30.00 nor greater than \$33.00 per common share, to the seller in cash. The tender offer expired on February 12, 2020.

On February 19, 2020, the Company announced the final results of its “modified Dutch Auction” tender offer. The Company accepted for purchase 14,000,000 shares of its common stock, \$0.01 par value per share, at a price of \$30 per share, for an aggregate cost of approximately \$420.0 million, excluding fees and expenses related to the tender offer. These shares represented approximately 32.67 percent of the shares outstanding. \$6.66 per share or total of \$93.24 million of these share repurchases have been classified to reduce common stock and \$23.34 per share or total of \$326.76 million of these share repurchases have been classified to reduce retained earnings in the accompanying consolidated balance sheet as of June 30, 2020.

From January through June 2020, 1.4 million shares of common stock were issued upon the exercise of stock options at a price of \$2.94 to \$19.09 per share for total proceeds of \$8.3 million.

6. 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 are 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 Plan adopted in 2005 may not, in aggregate, exceed 5% of the total number of outstanding common shares. The exercise price per common share under each option is 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, 2019	6,965,730	\$2.71 - \$21.99	6.09
Granted	81,500	8.89 - 14.77	14.88
Exercised	(1,377,761)	2.94 - 19.09	5.99
Forfeitures	(42,042)	4.95 - 21.80	9.56
Options outstanding at June 30, 2020	5,627,427	\$2.71 - \$21.99	6.19

As of June 30, 2020, there was approximately \$10.5 million of unrecognized compensation cost, related to stock options granted under the Plans which will be amortized to stock compensation expense over the next 1.64 years.

7. Net Income/Loss Per Share

The following summarizes the computation of basic and diluted net income/loss per share for three months and six months ended June 30, 2020 and 2019 (in thousands, except share and per share data):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Net loss	\$ (6,844)	\$ (5,852)	\$ (6,858)	\$ (11,716)
Weighted-average number of common shares—basic and diluted	28,856,085	37,519,697	32,512,789	36,752,820
Net loss per share—basic and diluted	\$ (0.24)	\$ (0.16)	\$ (0.21)	\$ (0.32)

8. Income Taxes

The Company did not record a tax provision during the three months ended June 30, 2019 due to the Company having no revenues or income prior to December 2019. During the three months ended June 30, 2020, the Company recorded an income tax benefit of \$332 thousand. The Company's effective income tax rate was 4.6% and 9.1% for the three and six months ended June 2020, respectively, compared to an effective income tax rate of 0% for the three and six months ended June 30, 2019.

The Company did not record a tax provision during the six months ended June 30, 2019 due to the Company having no revenues or income prior to December 2019. During the six months ended June 30, 2020, the Company recorded an income tax benefit of 684 thousand. The forecasted 2020 annual effective tax rate of 4.9% has been applied to net income before income taxes for the six months ended June 30, 2020. Further adjustments have been made for the tax effect of discrete tax benefits of stock compensation realized during the current period, resulting in a 9.1% effective tax rate for the six months ended June 30, 2020. The difference in the 27% Canadian statutory tax rate and the annual forecasted effective tax rate is primarily a result of the jurisdictional mix of earnings and losses, valuation allowances, and certain non-deductible compensation expenses. The Company maintains a valuation allowance against all deferred tax assets in Switzerland, Germany and Japan and certain deferred tax assets in the US and Canada in the current and forecasted annual periods that we concluded are not more-likely-than-not to be realizable.

9. Subsequent Events

The ongoing COVID-19 pandemic is disrupting our business operations, which we expect to continue throughout the remainder of 2020 and possibly beyond. We have experienced actual disruption to our supply chain regarding our ability to obtain syringes, and we have experienced or may experience difficulty obtaining masks, gloves and stoppers for vials, all of which are required in our manufacturing and/or clinical and drug discovery operations. Disruptions to manufacturing activities have already impacted our contractual arrangements with Janssen, causing Janssen to reduce its drug manufacturing orders under the clinical manufacturing agreement. Although we concluded that COVID-19 did not result in material adverse impacts on the Company's results of operations and financial position at June 30, 2020, if supply disruptions and purchase reductions continue, our clinical manufacturing revenue will be, and our clinical trial service revenue could be, adversely impacted. In addition, stay-at-home orders and social distancing restrictions imposed by national, state and local governments have required adjustments to staffing levels and may impact the willingness of employees to work in laboratory, manufacturing and clinical settings, even after these orders and restrictions are relaxed or allowed to expire. Ongoing restrictions and other disruptions related to COVID-19 could delay our efforts to identify, manufacture, enter into clinical studies, seek regulatory approvals or otherwise commercialize any product candidates.

On July 14, 2020, the Company announced the publication of data in the American Heart Association's journal, *Circulation*, that points to potential for XBiotech's drug candidate antibody that blocks interleukin-1 alpha (IL-1 α) for use as a therapeutic to reduce brain damage and neurological deficit after stroke. The publication is titled, *Post-Ischemic Administration of IL-1 α Neutralizing Antibody Reduces Brain Damage and Neurological Deficit in Experimental Stroke*, and reported that animals treated with anti-IL-1 α antibody had a 36% reduction in brain damage and these antibody treated animals retained significantly better neurological function compared to controls.

On July 22, 2020, the Company provided an update to its April 14 announcement and reported a milestone for the production of its new anti-IL-1 α therapy. The Company successfully cloned genes for a panel of new anti-IL-1 α antibodies discovered and characterized from a human donor earlier in 2020, into cells that can be used for production of these novel therapeutics. XBiotech's R&D team successfully engineered a cell-based production system for the first of its new anti-IL-1 α antibodies to enable the Company's drug manufacturing process, keeping the Company on target to re-enter the clinic in 2021.

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.

After the Janssen Transaction in December 2019, as of June 30, 2020, we had retained earnings of \$97.3 million. We had net losses before income tax of \$7.2 million and \$7.5 million for the three months and six months ended June 30, 2020, respectively, compared to \$5.9 million and \$11.7 million for the three months and six months ended June 30, 2019, respectively. During the next two years, we expect that the revenues from Janssen Transaction will generate enough cash for our research and development activities. However, 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 continue to operate as a public company, particularly following the end of the 2020 fiscal year when we lose our status as an emerging growth company and will be required to comply with additional obligations from which we are currently exempt, including the auditor attestation requirement for internal controls. We will need to generate significant revenues to achieve or sustain profitability, and we may never do so. As of June 30, 2020, we had 78 employees.

Impact of COVID-19 Pandemic

During the first and second quarter of 2020, we were subject to challenging social and economic conditions created as a result of the novel strain of coronavirus, SARS-CoV-2 (“COVID-19”). The resulting impact of the COVID-19 outbreak has created various impacts to our operations as a result of taking necessary precautions for essential personnel to operate safely both in person as well as remotely, disruptions in our supply chain and delays requested by Janssen in shipping drug product under our clinical manufacturing agreement.

We are currently operating our facilities at less than normal levels. Our office-based employees have been working from home since early March 2020, while ensuring essential staffing levels in our operations remain in place, including maintaining key personnel in our laboratories and manufacturing facilities. The Company considered the impact of COVID-19 on the assumptions and estimates used and determined that there were no material adverse impacts on the Company’s results of operations and financial position at June 30, 2020; however, this may not continue to be the case in future quarters. In addition to the delays we have already experienced in shipping drug product, it is possible that the COVID-19 pandemic and response efforts may adversely impact our future ability to manufacture clinical drugs for Janssen, which could have a material adverse impact on our results of operations or financial position during the remainder of 2020 or beyond. In addition, having a significant number of employees working remotely could increase our cybersecurity risk, create data accessibility concerns, and make us more susceptible to communication disruptions.

While we are currently continuing the clinical trials under the transition services agreement with Janssen, we expect that COVID-19 precautions may directly or indirectly impact the timeline for some of the clinical trials, which could delay or otherwise adversely affect our revenue and adversely impact our financial position. To help mitigate the impact to our clinical trials, we are pursuing innovative approaches such as remote monitoring, remote patient visits and supporting home infusions.

Due to the coronavirus pandemic, the Company failed to fully complete the manufacture of drugs specified for the March purchase order due to supply disruptions for the syringes used to hold the manufactured compound. We completed the manufacturing for this order in the second quarter of 2020. As of June 30, 2020, the Company had not completed the manufacture of drugs specified for the June purchase order due to additional syringe supply disruptions. We currently anticipate fulfilling all production volumes and returning to normal manufacturing capabilities under the clinical manufacturing agreement in the third quarter of 2020; however, due to the uncertainty associated with the pandemic and related mitigation efforts, it is possible this assessment could change in future periods as our manufacturing capabilities and Janssen’s purchase orders may continue to be negatively impacted.

On April 3, 2020, the Company announced a collaboration with BioBridge Global to participate in a U.S. Food and Drug Administration (FDA) investigational program for U.S. blood centers to begin collecting and distributing convalescent plasma from individuals who have recovered from COVID-19. The Company intends to use the blood samples to develop a candidate True Human™ antibody therapy for the disease.

Revenues

Prior to receiving payments under the clinical manufacturing agreement entered into in connection with the Janssen Transaction, we had not generated any revenue. Under this clinical manufacturing agreement, we manufacture bermekimab for use by Janssen in clinical trials, in exchange for fixed payments, paid in quarterly installments through 2021. For the three months and six months ended June 30, 2020, we have recorded \$4.5 million and \$7.5 million as manufacturing revenue.

In addition, we entered into a transition services agreement under which we agreed to continue operational management, on a fee-for-service basis, of certain ongoing clinical trials related to bermekimab. In consideration for all of the services to be provided, for each calendar quarter during the term of the transition services agreement, Janssen shall pay the Company a fee for such quarter equal to all pass-through costs incurred by the Company during such calendar quarter, plus a markup of 30%. For the three months and six months ended June 30, 2020, the Company has recorded \$11.0 and \$20.7 million gross clinical trial service revenue.

Our ability to generate any additional revenue and/or to become profitable (or sustain any profitability) depends on our ability to successfully commercialize any product candidates we may advance in the future. In 2020, the Company announced that a novel antibody it has discovered that neutralizes interleukin-1 alpha (IL-1 α) has now been advanced as a potential product candidate for clinical and commercial development. With the discovery, the Company is on schedule to reenter the clinic with a new anti-IL-1 α therapy in 2021. However, we are not able to estimate at this time the potential impact of the COVID-19 pandemic on our estimated timelines. It is possible that measures implemented to date or that may be implemented or re-implemented in the future by governmental authorities and/or our business partners in response to the pandemic may extend the timelines related to our development, clinical and commercial activities, which delays may be material and may adversely affect our revenues for future quarters, the current fiscal year or beyond.

Research and Development Expenses

Research and development expense consists of expenses incurred in connection with identifying and developing our drug candidates. These expenses consist primarily of salaries and related expenses, stock-based compensation, the purchase of equipment, laboratory and manufacturing supplies, facility costs, costs for preclinical and clinical research, development of quality control systems, quality assurance programs and manufacturing processes. We charge all research and development expenses to operations as incurred.

Clinical development timelines, likelihood of success and total costs vary widely. We do not currently track our internal research and development costs or our personnel and related costs on an individual drug candidate basis. We use our research and development resources, including employees and our drug discovery technology, across multiple drug development programs. As a result, we cannot state precisely the costs incurred for each of our research and development programs or our clinical and preclinical drug candidates. From inception through June 30, 2020, we have recorded total research and development expenses, including share-based compensation, of \$213.6 million. Our total research and development expenses for the three months and six months ended June 30, 2020 were \$2.6 million and \$3.7 million, respectively, compared to \$4.7 million and \$9.2 million for the three months and six months ended June 30, 2019, respectively. Share-based compensation accounted for \$1.2 million and \$1.7 million for the three months and six months ended June 30, 2020, respectively, compared to \$0.3 million and \$0.6 million for the three months and six months ended June 30, 2019, respectively.

Research and development expenses, as a percentage of total operating expenses for the three months and six months ended June 30, 2020 were 29% and 27%, respectively, compared to 78% for both the three months and six months ended June 30, 2019. The percentages, excluding share-based compensation, for the three months and six months ended June 30, 2020 were both 24%, compared to 80% for both the three months and six months ended June 30, 2019.

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. In addition, our ability to conduct research and other laboratory activities, to engage in clinical studies and to pursue regulatory approvals may be delayed or otherwise adversely impacted by measures implemented by governmental authorities and/or our business partners in response to the COVID-19 pandemic.

General and Administrative Expenses

General and administrative expense consists primarily of salaries and related expenses for personnel in administrative, finance, business development and human resource functions, as well as the legal costs of pursuing patent protection of our intellectual property and patent filing and maintenance expenses, stock-based compensation, and professional fees for legal services. Our total general and administration expenses for the three months and six months ended June 30, 2020 were \$6.2 million and \$10.3 million, respectively, compared to \$1.3 million and \$2.6 million for the three months and six months ended June 30, 2019, respectively. Share-based compensation accounted for \$1.9 million and \$4.0 million for the three months and six months ended June 30, 2020, respectively, compared to \$0.2 million and \$0.5 million for the three months and six months ended June 30, 2019, respectively.

General and administrative expenses, as a percentage of total operating expenses for the three months and six months ended June 30, 2020 were 71% and 73%, respectively, compared to 22% for both the three months and six months ended June 30, 2019. The percentages, excluding share-based compensation, for the three months and six months ended June 30, 2020 were both 76%, compared to 20% for both the three months and six months ended June 30, 2019.

Critical Accounting Policies

Our Management's Discussion and Analysis of Financial Condition and Results of Operations is based on our financial statements, which have been prepared in conformity with generally accepted accounting principles in the United States (US GAAP). The preparation of our financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and expenses incurred during the reported periods.

We base estimates on our historical experience, known trends and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Our significant accounting policies are more fully described in the notes to our financial statements appearing in this Quarterly Report on Form 10-Q.

Income Taxes

We account for income taxes under the asset and liability method. We record deferred tax assets and liabilities for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases, as well as for operating loss and tax credit carryforwards. We measure deferred tax assets and liabilities using enacted tax rates expected to apply to taxable income in the

years in which we expect to recover or settle those temporary differences. We recognize the effect of a change in tax rates on deferred tax assets and liabilities in the results of operations in the period that includes the enactment date. We assess the likelihood that deferred tax assets will be realized, and we recognize a valuation allowance if it is more likely than not that some portion of the deferred tax assets will not be realized. This assessment requires judgment as to the likelihood and amounts of future taxable income by tax jurisdiction. To date, we have provided a valuation allowance against our deferred tax assets as we believe the objective and verifiable evidence of our historical pretax net losses outweighs any positive evidence of our forecasted future results. Although we believe that our tax estimates are reasonable, the ultimate tax determination involves significant judgment. We will continue to monitor the positive and negative evidence and will adjust the valuation allowance as sufficient objective positive evidence becomes available.

We account for uncertain tax positions by recognizing the financial statement effects of a tax position only when, based upon technical merits, it is more likely than not that the position will be sustained upon examination. We recognize potential accrued interest and penalties associated with unrecognized tax positions within our global operations in income tax expense.

Results of Operations

Revenue

Revenue during the three months ended and six months ended June 30, 2020 and 2019 are summarized as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Revenue				
Manufacturing revenue	\$ 4,500	\$ -	\$ 7,500	\$ -
Clinical Trial revenue	10,998	-	20,679	-
Total revenue	\$ 15,498	\$ -	\$ 28,179	\$ -

We had not generated any revenue before the year 2020. Under the clinical manufacturing agreement with Janssen, for the three months ended June 30, 2020, we have recorded \$4.5 million as manufacturing. Clinical trial revenue for the three months ended June 30, 2020 is based on the transition services agreement under which we agreed to continue operational management, on a fee-for-service basis, of certain ongoing clinical trials related to bermekimab, which includes \$8.5 million pass-through expense for two ongoing trials and \$2.5 million mark-up revenue.

We have recorded \$7.5 million manufacturing revenue for the six months ended June 30, 2020. Clinical trial revenue for the six months ended June 30, 2020 is \$20.7 million, including \$15.9 million pass-through expense for two ongoing trials and \$4.8 million mark-up revenue. Our first and second quarter results may not be indicative of future revenues or costs associated with our clinical manufacturing or clinical trial management agreements due to the ongoing impact of the COVID-19 pandemic.

Cost of Goods Sold

Cost of goods sold during the three months and six months ended June 30, 2020 and 2019 are summarized as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Cost of goods sold				
Manufacturing cost	\$ 3,956	\$ -	\$ 6,122	\$ -
Clinical trial cost	9,245	-	16,753	-
Total cost of goods sold	\$ 13,201	\$ -	\$ 22,875	\$ -

We had not incurred any cost of goods sold before the year 2020. The manufacturing cost for the three months ended June 30, 2020 represents period expense for manufacturing, quality assurance and quality control departments. Clinical trial cost for the three months ended June 30, 2020 is \$9.2 million, which is the pass-through expenses for two ongoing trials and other related clinical trial department expenses.

We have recorded \$6.1 million manufacturing cost for the six months ended June 30, 2020. Clinical trial cost for the six months ended June 30, 2020 is \$16.8 million including the pass-through expenses for two ongoing trials and other related clinical trial department expenses. Our first and second quarter results may not be indicative of future revenues or costs associated with our clinical manufacturing or clinical trial management agreements due to the ongoing impact of the COVID-19 pandemic.

Expenses

Research and Development

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

	Three Months Ended June 30,		Increase	% Increase
	2020	2019	(Decrease)	(Decrease)
Salaries and related expenses	\$ 354	\$ 1,183	\$ (829)	-70%
Laboratory and manufacturing supplies	136	1,344	(1,208)	-90%
Clinical trials and sponsored research	594	241	353	146%

Stock-based compensation	1,214	291	923	317%
Other	267	1,634	(1,367)	-84%
Total	\$ 2,565	\$ 4,693	\$ (2,128)	-45%

	Six Months Ended June 30,		Increase	% Increase
	2020	2019	(Decrease)	(Decrease)
Salaries and related expenses	\$ 675	\$ 2,349	\$ (1,674)	-71%
Laboratory and manufacturing supplies	261	2,586	(2,325)	-90%
Clinical trials and sponsored research	594	496	98	20%
Stock-based compensation	1,747	586	1,161	198%
Other	443	3,203	(2,761)	-86%
Total	\$ 3,720	\$ 9,220	\$ (5,500)	-60%

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 45% to \$2.6 million for the three months ended June 30, 2020 compared to \$4.7 million for the three months ended June 30, 2019. Research and development expenses also decreased 60% to 3.7 million for the six months ended June 30, 2020 compared to \$9.2 million for the six months ended June 30, 2019.

The three months and six months decrease was mainly due to classification of certain expenses to cost of goods sold. Manufacturing department expenses are classified to cost of goods sold as a result of the clinical manufacturing agreement we entered into as part of the Janssen Transaction. Clinical trial expenses are generated from the two ongoing trials. The expenses pursuant to the Transition Services Agreement entered into as part of the Janssen Transaction were classified as cost of goods sold. Our first and second quarter results may not be indicative of future revenues or costs associated with our clinical manufacturing or clinical trial management agreements due to the ongoing impact of the COVID-19 pandemic. The stock-based compensation increased due to the new grants to employees and Chief Executive Officer in the fourth quarter of 2019.

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General and Administrative

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

	Three Months Ended June 30,		Increase	% Increase
	2020	2019	(Decrease)	(Decrease)
Salaries and related expenses	\$ 2,979	\$ 211	\$ 2,768	1312%
Patent filing expense	131	170	(39)	-23%
Stock-based compensation	1,872	195	1,677	860%
Professional fees	641	356	285	80%
Other	623	381	242	64%
Total	\$ 6,246	\$ 1,313	\$ 4,933	376%

	Six Months Ended June 30,		Increase	% Increase
	2020	2019	(Decrease)	(Decrease)
Salaries and related expenses	\$ 3,237	\$ 466	\$ 2,771	595%
Patent filing expense	270	369	(99)	-27%
Stock-based compensation	4,016	470	3,546	754%
Professional fees	1,579	540	1,039	192%
Other	1,167	746	421	56%
Total	\$ 10,269	\$ 2,591	\$ 7,678	296%

General and administrative expenses increased to \$6.2 million for the three months ended June 30, 2020 compared to \$1.3 million for the three months ended June 30, 2019. General and administrative expenses increased to \$10.3 million for the six months ended June 30, 2020 compared to \$2.6 million for the six months ended June 30, 2019.

The three months increase was primarily related to stock-based compensation expenses of \$1.7 million, due to the new grants to employees and Chief Executive Officer in the fourth quarter of 2019. Salaries and related expense increased due to the \$2.7 million bonus to the Chief Executive Officer in June 2020.

Compared to the six months ended June 30, 2019, the general and administrative expense increase in the six months ended June 30, 2020 was primarily caused by the increase to stock-based compensation expense. Salaries and related expense increased due to the \$2.7 million bonus to the Chief Executive Officer in June 2020. Also, professional fees increased \$1.0 million mainly due to professional and legal fees related to the tender offer completed in February 2020.

Other income (loss)

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

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2020	2019	2020	2019
Interest income	\$ 306	\$ 51	\$ 2,204	\$ 129

Other income (loss)	(503)	1	(503)	10
Foreign exchange gain (loss)	(465)	102	(558)	(44)
Total	<u>\$ (662)</u>	<u>\$ 154</u>	<u>\$ 1,143</u>	<u>\$ 95</u>

The interest income for the three months and six months ended June 30, 2020 and 2019 was mainly from the interest generated from the Company's Canadian bank account and escrow account. The other expense for the three months and six months ended June 30, 2020 was a charitable donation. Foreign exchange gain (loss) was mainly due to the fluctuation between the US dollar and the Euro, and the US dollar and the Canadian dollar in the three months and six months ended June 30, 2020 compared to 2019.

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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. In addition, the duration and extent of measures that have been or may in the future be adopted by XBiotech or our business partners, or imposed by governmental authorities, in response to the COVID-19 pandemic may require the use of additional cash resources and adversely impact our liquidity. We are currently unable to estimate the severity or duration of these potential impacts to our liquidity and capital resources.

Since our inception on March 22, 2005 through June 30, 2020, we have funded our operations principally through private placements and public offerings of equity securities, which have provided aggregate cash proceeds of approximately \$307.8 million. We received \$675 million in cash proceeds from the Janssen Transaction in the year ended December 31, 2019. We will receive \$75 million cash from the same transaction in 2021. The following table summarizes our sources and uses of cash (in thousands):

Net cash (used in) provided by:	Six Months Ended June 30,	
	2020	2019
Operating activities	\$ (72,241)	\$ (9,540)
Investing activities	(815)	(37)
Financing activities	(411,804)	38,636
Effect of foreign exchange rate on cash and cash equivalents	(31)	39
Net change in cash and cash equivalents	<u>\$ (484,891)</u>	<u>\$ 29,098</u>

During the six months ended June 30, 2020 and 2019, our operating activities used net cash of \$72.2 million and \$9.5 million, respectively. The use of net cash in each of these periods primarily resulted from our net losses. The net cash used in operating activities for the six months ended June 30, 2020 as compared to the six months ended June 30, 2019 was mainly due to the \$51.1 million income tax payment for 2019.

During the six months ended June 30, 2020 and 2019, our investing activities used net cash of \$815 thousand and \$37 thousand, respectively. The use of cash was for the purchase of new research and development equipment.

During the six months ended June 30, 2020 and 2019, our financing activities used net cash of \$411.8 million and provided net cash proceeds of \$38.6 million, respectively. During the six months ended June 30, 2020, employees exercised stock options to purchase a total of 1.4 million shares of our common stock for approximately \$8.3 million in net proceeds. On February 19, 2020, we used approximately \$420 million to purchase 14,000,000 common shares at a price of \$30.00 per share, relating to the tender offer completed in February 2020. During the six months ended June 30, 2019, the Company sold 4.8 million shares under the Common Shares Purchase Agreement with Piper Jaffray & Co for net proceeds of approximately \$37.5 million. Employees exercised stock options to purchase a total of 255 thousand shares of our common stock for approximately \$0.9 million in net proceeds.

We expect to continue to incur operating losses in the future. Although we are currently receiving clinical manufacturing revenue and clinical trial service revenue from Janssen, 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 June 30, 2020, our principal sources of liquidity were our cash and cash equivalents, which totaled approximately \$229.7 million. The ongoing impact of COVID-19 may delay or reduce our expected revenues from the Janssen Transaction. If we determine in the future that we require additional capital, we may face difficulties in conducting common stock offerings, as a result of market volatility caused by continued effects of COVID-19 affecting the global economy.

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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 About 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 quarter ended June 30, 2020 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, 2019, except for the following:

Our business may be adversely affected by the ongoing COVID-19 pandemic.

Beginning in late 2019, the outbreak of COVID-19 has evolved into a global pandemic that is disrupting our business operations, which we expect to continue throughout the remainder of 2020 and possibly beyond. Depending upon the length and severity of the pandemic, which cannot be predicted, we may continue to experience disruptions that could materially and adversely impact our business including:

- In March 2020 we were unable to fully complete the manufacture of drugs specified under our purchase order from Janssen due to an inability to obtain an adequate number of the syringes used to hold the manufactured compound. As of June 30, 2020, the Company had not completed the manufacture of drugs specified for the June purchase order due to additional syringe supply disruptions. We also have experienced or may experience difficulty obtaining masks, gloves and stoppers for vials, all of which are required in our manufacturing and/or clinical and drug discovery operations. If these or any other third parties in our supply chain are or continue to be adversely impacted by restrictions resulting from the COVID-19 pandemic, including staffing shortages, production slowdowns, or disruptions in freight and other transportation services and delivery distribution systems, our supply chain may be disrupted, which would limit our ability to manufacture our product candidates for our clinical trials, to meet our obligations to manufacture drugs for Janssen under our clinical manufacturing agreement, or to conduct our research, development and clinical operations.
- The pandemic has already affected and may continue to affect our obligations and performance under our agreements with Janssen. In addition to the production issues described above caused by the syringe shortage, in March 2020, Janssen reduced its drug manufacturing order and requested that we delay shipment of drugs that we had already completed manufacturing. Additionally, as of June 30, 2020, the Company had not completed the manufacture of drugs specified for the June purchase order due to additional syringe supply disruptions. We cannot predict the likely potential adverse impact of COVID-19 on Janssen's future purchase orders or our ability to complete the manufacturing required by those purchase orders.
- Various aspects of our clinical trials could be limited or take longer than expected, including delays or difficulties in enrolling patients in our clinical trials, in clinical trial site initiation, and in recruiting clinical site investigators and clinical site staff; increased rates of patients withdrawing from clinical trials; diversion of healthcare resources away from the conduct of clinical trials; interruption of key clinical trial activities such as clinical trials site data monitoring due to limitations on travel imposed or recommended by governmental authorities; impact on employees and others or interruption of clinical trial visits or study procedures which may impact the integrity of subject data and clinical study endpoints; and interruption or delays in the operations of the FDA and comparable foreign regulatory agencies, which may impact regulatory review and approval timelines.
- The FDA and comparable foreign regulatory agencies may experience disruptions, have slower response times or be under-resourced to continue to monitor our clinical trials or to conduct required activities and review of our product candidates seeking regulatory review and such disruptions could materially affect the development, timing and approval of our product candidates.

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- As a result of market volatility caused by continued effects of COVID-19 affecting the global economy, we may face difficulties raising capital through sales of our common stock or other securities at acceptable prices, on acceptable terms or at all.

The COVID-19 pandemic continues to rapidly evolve. The ultimate impact of the pandemic on us is highly uncertain and subject to change and will depend on future developments, which cannot be accurately predicted. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, our research programs, our clinical manufacturing or clinical trial management agreements, the healthcare system or the global economy. Given the uncertainties, we may be unable to maintain operations as planned prior to the COVID-19 pandemic.

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, 2019, any of which risks and uncertainties may be further exacerbated by the COVID-19 pandemic and could materially affect our business, financial condition or future results. The risks described in this Quarterly Report on Form 10-Q and 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.

- [10.1](#) [Second Amendment to the XBiotech Inc. 2015 Equity Incentive Plan \(incorporated by reference to Annex A to the Registrant's Definitive Proxy Statement on Schedule 14A filed on April 28, 2020\)](#)
- [10.2](#) [Third Amendment to the XBiotech Inc. 2015 Equity Incentive Plan \(incorporated by reference to Annex B to the Registrant's Definitive Proxy Statement on Schedule 14A filed on April 28, 2020\)](#)
- [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 June 30, 2020, formatted in Inline Xtensible Business Reporting Language (iXBRL): (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).
- 104 Cover Page Interactive Data File (embedded within the iXBRL document).

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: August 10, 2020

XBIOTECH INC.

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

Date: August 10, 2020

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: August 10, 2020

/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: August 10, 2020

/S/ QUEENA HAN

Queen 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 June 30, 2020 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: August 10, 2020

In connection with the Quarterly Report of XBiotech Inc. on Form 10-Q for the period ended June 30, 2020, 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

Queen Han
Vice President, Finance and Human Resources and Secretary
(Principal Financial Officer)
Date: August 10, 2020