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, 2021

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	☐	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☒
		Emerging growth company	☐

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

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

As of August 9, 2021, there were 30,378,209 shares of the Registrant's common stock issued and outstanding.

XBIOTECH INC.
THREE MONTHS AND SIX MONTHS ENDED JUNE 30, 2021
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PART I—FINANCIAL INFORMATION

PART II—OTHER INFORMATION

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;*

- *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, 2020 filed with the SEC on March 16, 2021, 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.

XBiotech Inc.

Consolidated Balance Sheets
(in thousands, except share data)

	June 30, 2021 (Unaudited)	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 315,258	$ 237,366
Accounts receivable	25	4,113
Escrow receivable	-	75,063
Deferred cost of goods sold	1,089	2,177
Income tax receivable	8,109	6,574
Prepaid expenses and other current assets	382	582
Total current assets	324,863	325,875
Deferred tax asset	642	533
Property and equipment, net	28,451	27,336
Total assets	$ 353,956	$ 353,744
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	$ 1,491	$ 2,491
Accrued expenses	1,681	1,351
Income tax payable	719	142
Total current liabilities	3,891	3,984
Long-term liabilities:		
Income tax payable	1,393	1,121
Deferred tax liability	108	-
Total liabilities	5,392	5,105
Shareholders' equity:		
Preferred Stock, no par value, unlimited shares authorized, no shares outstanding	-	-
Common stock and additional paid in capital, no par value, unlimited shares authorized, 30,024,007 and 29,304,396 shares outstanding at June 30, 2021 and December 31, 2020, respectively	256,779	249,805
Accumulated other comprehensive income	1,903	1,266
Accumulated equity	89,882	97,568
Total shareholders' equity	348,564	348,639
Total liabilities and shareholders' equity	$ 353,956	$ 353,744

See accompanying notes.

XBiotech Inc.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021 (unaudited)	2020 (unaudited)	2021 (unaudited)	2020 (unaudited)
Revenue				
Manufacturing revenue	$ 4,500	$ 4,500	$ 9,000	$ 7,500
Clinical trial service revenue	25	10,998	375	20,679
Total revenue	4,525	15,498	9,375	28,179
Cost of goods sold				
Manufacturing cost	1,341	3,956	3,376	6,122
Clinical trial cost	19	9,245	288	16,753
Total cost of goods sold	1,360	13,201	3,664	22,875
Gross margin	3,165	2,297	5,711	5,304
Operating expenses:				
Research and development	9,254	2,565	13,888	3,720
General and administrative	4,516	6,246	5,981	10,269
Total operating expenses	13,770	8,811	19,869	13,989
Loss from operations	(10,605)	(6,514)	(14,158)	(8,685)
Other income (loss):				
Interest income	123	306	232	2,204
Other income (loss)	(2)	(503)	(11)	(503)
Foreign exchange gain (loss)	793	(465)	1,202	(558)
Total other income (loss)	914	(662)	1,423	1,143
Loss before income taxes	(9,691)	(7,176)	(12,735)	(7,542)
Benefit for income taxes	4,573	332	5,049	684
Net loss	$ (5,118)	$ (6,844)	$ (7,686)	$ (6,858)
Net loss per share—basic and diluted	$ (0.17)	$ (0.24)	$ (0.26)	$ (0.21)
Shares used to compute basic net loss per share	29,987,917	28,856,085	29,707,352	32,512,789

See accompanying notes.

XBiotech Inc.

Consolidated Statements of Comprehensive Loss
(in thousands)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021 (unaudited)	2020 (unaudited)	2021 (unaudited)	2020 (unaudited)
Net loss	$ (5,118)	$ (6,844)	$ (7,686)	$ (6,858)
Foreign currency translation adjustment	318	(121)	637	(31)
Comprehensive loss	$ (4,800)	$ (6,965)	$ (7,049)	$ (6,889)

See accompanying notes.

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

	Number of Shares	Common Stock and Additional Paid in Capital	Accumulated Other Comprehensive Income	Accumulated Equity (Deficit)	Total
Balance at March 31, 2021	29,983	$ 255,513	$ 1,585	$ 95,000	$ 352,098
Net loss	-	-	-	(5,118)	(5,118)
Foreign currency translation adjustment	-	-	318	-	318
Issuance of common stock under stock option plan	41	226	-	-	226
Share-based compensation expense	-	1,040	-	-	1,040
Balance at June 30, 2021	30,024	256,779	1,903	89,882	348,564

	Number of Shares	Common Stock and Additional Paid in Capital	Accumulated Other Comprehensive (Loss)	Accumulated Equity (Deficit)	Total
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	28,897	246,395	(137)	97,312	343,570

	Number of Shares	Common Stock and Additional Paid in Capital	Accumulated Other Comprehensive Income	Accumulated Equity (Deficit)	Total
Balance at December 31, 2020	29,304	249,805	1,266	97,568	$ 348,639
Net loss	-	-	-	(7,686)	(7,686)
Foreign currency translation adjustment	-	-	637	-	637
Issuance of common stock under stock option plan	720	4,998	-	-	4,998
Share-based compensation expense	-	1,976	-	-	1,976
Balance at June 30, 2021	30,024	256,779	1,903	89,882	348,564

	Number of Shares	Common Stock and Additional Paid in Capital	Accumulated Other Comprehensive (Loss)	Accumulated Equity (Deficit)	Total
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	28,897	246,395	(137)	97,312	343,570

See accompanying notes.

XBiotech Inc.

Consolidated Statements of Cash Flows
(in thousands)

	Six Months Ended June 30, 2021 (unaudited)	2020 (unaudited)
Operating activities		
Net loss	$ (7,686)	$ (6,858)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation	1,259	1,104
Share-based compensation expense	1,976	6,631
Changes in operating assets and liabilities:		
Account receivable	4,088	(20,679)
Income tax receivable	(1,535)	(4,975)
Deferred cost of goods sold	1,089	(2,230)
Escrow receivable	75,063	(48)
Prepaid expenses and other current assets	200	868
Deferred tax assets	(108)	-
Accounts payable	(1,026)	3,091
Accrued expenses	330	651
Contract liabilities	-	(4,500)
Deferred Revenue	-	1,500
Income tax payable	848	(46,796)
Deferred tax liability	108	-
Net cash provided by (used in) operating activities	74,606	(72,241)
Investing activities		
Purchase of property and equipment	(2,349)	(815)
Net cash used in investing activities	(2,349)	(815)
Financing activities		
Share repurchases of common stock and warrants, net	-	(420,000)
Issuance of common stock under stock option plan	4,998	8,258
Subscription receivable	-	(62)
Net cash provided by (used in) financing activities	4,998	(411,804)
Effect of foreign exchange rate on cash and cash equivalents	637	(31)
Net change in cash and cash equivalents	77,892	(484,891)
Cash and cash equivalents, beginning of period	237,366	714,594
Cash and cash equivalents, end of period	$ 315,258	$ 229,703
Supplemental Information:		
Accrued purchases of property and equipment	25	-

See accompanying notes.

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 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 disease. At the heart of the Company is a proprietary technical knowhow to translate natural human immunity into therapeutic product candidates.

An area of medical focus for XBiotech are therapies that block a potent substance naturally produced by body, known as interleukin-1 alpha (IL-1a), that mediates tissue breakdown, angiogenesis, the formation of blood clots and inflammation. IL-1a is a protein that is on or in cells of the body and is involved in the body's response to injury or trauma. In almost all chronic and in some acute injury scenarios (such as stroke or heart attack), IL-1a may mediate harmful disease-related activity.

At the end of 2019, XBiotech sold a True Human™ antibody that blocked IL-1a activity for $1.35 billion in cash and potential milestone payments (the "Janssen Transaction"). As part of the Janssen Transaction, XBiotech maintained the right to develop new antibodies that block IL-1a and develop these therapeutics in all areas of medicine except dermatology. Moreover, all patents acquired by Janssen relating to IL-1a would be asserted for the benefit of XBiotech to protect its future IL-1a related therapies in all non-dermatological indications. Consequently, XBiotech is pursuing the development of other True Human™ antibodies targeting IL-1a for areas of medicine outside of dermatology. Due to the speed and effectiveness of the Company's True Human™ antibody discovery technology, the Company has identified new IL-1a targeting product candidates and has already brought one such candidate into a clinical study in oncology. While the Company previously was focused on a single True Human™ antibody targeting IL-1a, it now plans to develop more than one product candidate that targets IL-1a to be used in different areas of medicine.

The Company continues to be subject to a number of risks common to companies in similar stages of development. Principal among these risks are the uncertainties of technological innovations, dependence on key individuals, development of the same or similar technological innovations by the Company's competitors and protection of proprietary technology. The Company's ability to fund its planned clinical operations, including completion of its planned trials, is expected to depend on the amount and timing of cash receipts from future collaboration or product sales and/or financing transactions. The Company believes that its cash and cash equivalents of $315.3 million at June 30, 2021, will enable the Company to achieve several major inflection points, including potential new clinical studies with its lead product candidate. The Company expects to have sufficient cash through the foreseeable future 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, 2021 and December 31, 2020, the results of its operations and comprehensive loss for the three months and six months periods ended June 30, 2021 and 2020, and the cash flows for the six months periods ended June 30, 2021 and 2020.

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 to Janssen 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

The Company has a Clinical Manufacturing Agreement that it accounts for by analogy to ASC 606, under which it agreed to manufacture bermekimab for use by Janssen in clinical trials, in exchange for payments of $4.5 million per quarter, 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 the Company expects to meet these standards.

Clinical Trial Service Revenue

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. The arrangement may continue as long as the clinical trials are ongoing; however, Janssen may terminate the contract at any time with 30 days notice.

Research and Development Costs

All research and development costs are charged to expense as incurred. Research and development costs include salaries and personnel-related costs, consulting fees, fees paid for contract clinical trial research services, the costs of laboratory consumables, equipment and facilities, license fees and other external costs. Costs incurred to acquire licenses for intellectual property to be used in research and development activities with no alternative future use are expensed as incurred as research and development costs.

Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are deferred and capitalized. The capitalized amounts are expensed as the related goods are delivered or the services are performed.

Clinical Trial Accruals

Expense accruals related to clinical trials are based on the Company's estimates of services received and efforts expended pursuant to contracts with third party service providers conduct and manage clinical trials on the Company's behalf. The financial terms of these agreements vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing costs, the Company estimates the period over which services will be performed and the level of effort to be expended in each period based upon patient enrollment, clinical site activations, or information provided to the Company by its vendors on their actual costs incurred. Any estimates of the level of services performed or the costs of these services could differ from actual results.

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 provision for income taxes, including the estimation of its taxable income or loss for the full fiscal year. The Company has accumulated significant deferred tax assets that reflect the tax effects of net operating losses and tax credit carryovers and temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Realization of 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 to 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.

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, 2021 and 2020 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,	
	2021	2020	2021	2020
Research and development	$ 433	$ 1,214	$ 796	$ 1,747
General and administrative	534	1,872	1,046	4,016
Cost of goods sold	73	90	134	868
Total share-based compensation expense	$ 1,040	$ 3,176	$ 1,976	$ 6,631

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,					
	2021			2020			2021			2020		
Dividend yield		-			-			-			-	
Expected volatility	84%	-	85%	88%			84%	-	86%	88%	-	91%
Risk-free interest rate	0.9%	-	1.1%	0.43%	-	0.47%	0.5%	-	1.1%	0.42%	-	1.87%
Expected life (in years)	5.38	-	6.25	6.25			5.38	-	6.25	6.25	-	10
Weighted-average grant date fair value per share		11.12			14.02			11.49			14.88	

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 date (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, 2021 and December 31, 2021, 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, 2021.

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 ASU No. 2016-13, Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments. This ASU requires instruments measured at amortized cost to be presented at the net amount expected to be collected. Entities are also required to record allowances for available-for-sale debt securities rather than reduce the carrying amount. On November 15, 2019, the FASB delayed the effective date of the standard for certain small public companies and other private companies. As amended, the effective date of ASC Topic 326 was delayed until fiscal years beginning after December 15, 2022 for SEC filers that are eligible to be smaller reporting companies under the SEC's definition, as well as private companies and not-for-profit entities. The Company expects that the adoption will not have a material impact on its 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. The Company early adopted ASU 2019-12 as of January 1, 2020. The adoption of ASU 2019-12 resulted in no material impact to the Company's financial statements.

3. Revenue

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, 2021, the Company has recorded $4.5 and $9.4 million of gross revenue under this arrangement with the corresponding expense to clinical services cost of goods sold.

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 2021.

4. Property and Equipment

Property and equipment consisted of the following as of June 30, 2021 and December 31, 2020 (in thousands):

	June 30, 2020	December 31, 2020
Manufacturing equipment	$ 3,652	$ 3,966
Winnebago building	21,327	20,473
Other fixed assets	3,472	2 ,897
Total property and equipment	$ 28,451	$ 27,336

5. Common Stock

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

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. $6.99 per share or total of $97.9 million of these shares repurchases have been classified to reduce common stock and $23.34 per share or total of $322.1 million of these shares repurchases have been classified to reduce retained earnings in the accompanying consolidated balance sheet as of December 31, 2020.

From January through December 31, 2020, 1.8 million shares of common stock were issued upon the exercise of stock options at a price of $2.71 to $19.09 per share for total proceeds of $10.3 million.

From January through June 30, 2021, 743 thousand shares of common stock were issued upon the exercise of stock options at a price of $2.71 to $21.99 per share for total proceeds of $5.1 million.

6. Common Stock Options

On November 11, 2005, the Board of Directors of the Company adopted the XBiotech Inc. 2005 Incentive Stock Option Plan (the “2005 Plan”), and on March 24, 2015, the board of directors of the Company adopted the XBiotech Inc. 2015 Equity Incentive Plan (the 2015 Plan”) pursuant to which the Company may grant incentive stock and non-qualified stock options to directors, officers, employees or consultants of the Company or an affiliate or other persons as the Compensation Committee may approve.

All options under both Plans will be non-transferable and may be exercised only by the participant, or in the event of the death of the participant, a legal representative until the earlier of the options’ expiry date or the first anniversary of the participant’s death, or such other date as may be specified by the Compensation Committee.

The term of the options is at the discretion of the Compensation Committee, but may not exceed 10 years from the grant date. The options expire on the earlier of the expiration date or the date three months following the day on which the participant ceases to be an officer or employee of or consultant to the Company, or in the event of the termination of the participant with cause, the date of such termination. Options held by non-employee Directors have an exercise period coterminous with the term of the options.

The number of common shares reserved for issuance to any one person pursuant to the 2005 Plan shall not, in aggregate, exceed 5% of the total number of outstanding common shares. The exercise price per common share under each option will be the fair market value of such shares at the time of the grant. Upon stock option exercise, the Company issues new shares of common stock.

A summary of changes in common stock options issued under the 2005 Plan and under the 2015 Plan is as follows:

	Options	Exercise Price			Weighted-Average Exercise Price
Options outstanding at December 31, 2020	5,327,425	$2.71	-	$21.99	6.09
Granted	130,000	15.83	-	17.49	16.69
Exercised	(743,279)	2.71	-	21.99	6.87
Forfeitures	(88,374)	4.14	-	19.30	9.55
Options outstanding at June 30, 2021	4,625,772	$2.71	-	$21.99	16.30

As of June 30, 2021, there was approximately $5.1 million of unrecognized compensation cost, related to stock options granted under the Plans which will be amortized to stock compensation expense over the next 1.58 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, 2021 and 2020 (in thousands, except share and per share data):

	Three Months Ended June 30, 2021	Six Months Ended June 30, 2020	2021	2020
Net loss	$ (5,118)	$ (6,844)	$ (7,686)	$ (6,858)
Weighted-average number of common shares—basic and diluted	29,987,917	28,856,085	29,707,352	32,512,789
Net loss per share—basic and diluted	$ (0.17)	$ (0.24)	$ (0.26)	$ (0.21)

8. Income Taxes

During the three months ended June 30, 2020 , the Company recorded an income tax benefit of $332 thousand. During the three months ended June 30, 2021, the Company recorded an income tax benefit of $4.57 million. The forecasted 2021 annual effective tax rate of 31.5% has been applied to net income before income taxes for the six months ended June 30, 2021. The effective tax rate for the six months ended June 30, 2021 was 39.65%, including amounts recorded for discrete events.

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, foreign exchange gains and losses, and permanently disallowed stock and executive compensation expenses. The Company maintains a valuation allowance against all deferred tax assets in Germany and the US, and certain deferred tax assets in Canada in the current and forecasted annual periods that we concluded are not more-likely-than-not to be realizable. The forecasted income tax benefit is primarily related to the ability to carry back losses in Canada to a prior year.

As of December 31, 2020, there are $2.4 million of unrecognized tax benefits recorded as a liability on the Company’s financials. There was a $271 thousand increase in the liability during the six months ended June 30, 2021.

9. Subsequent Events

On July 6, 2021, XBiotech Inc. announced that its Board of Directors declared an extraordinary cash dividend of approximately $2.50 per share, or up to an aggregate of $75 million, payable on July 23, 2021, to stockholders of record as of the close of business July 16, 2021. Based on the number of shares of Common Stock issued and outstanding on the record date for the dividend, each such holder received $2.47 per share on July 23, 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 and the tender offer in February 2020, we had retained earnings of $89.9 million. We had net losses before income tax of $9.7 million and $12.7 million for the three months and six months ended June 30, 2021, respectively, compared to $7.2 million and $7.5 million for the three months and six months ended June 30, 2020, respectively. During the next year, we expect that the revenues from Janssen Transaction will generate enough cash for our research and development activities However, the term of the clinical manufacturing agreement will end on December 31, 2021. In addition, 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. We will need to generate significant revenues to achieve or sustain profitability, and we may never do so. As of June 30, 2021, we had 94 employees.

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 the clinical manufacturing agreement, we manufacture bermekimab for use by Janssen in clinical trials, in exchange for fixed payments, paid in quarterly installments through 2021. Following the end of 2021, the agreement will expire and we will not be entitled to receive any more such revenues. 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. 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.

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, 2021, we have recorded total research and development expenses, including share-based compensation, of $233.2 million. Our total research and development expenses for the three months and six months ended June 30, 2021 were $9.3 million and $13.9 million, respectively, compared to $2.6 million and $3.7 million for the three months and six months ended June 30, 2020, respectively. Share-based compensation accounted for $0.4 million and $0.8 million for the three months and six months ended June 30, 2021, respectively, compared to $1.2 million and $1.7 million for the three months and six months ended June 30, 2020, respectively.

Research and development expenses, as a percentage of total operating expenses for the three months and six months ended June 30, 2021 were 67% and 70%, respectively, compared to 29% and 27% for both the three months and six months ended June 30, 2020. The percentages, excluding share-based compensation, for the three months and six months ended June 30, 2021 were 69% and 73%, respectively, compared to 24% for both the three months and six months ended June 30, 2020.

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

Based on the results of our preclinical studies, we anticipate that we will select drug candidates and research projects for further development on an ongoing basis in response to their preclinical and clinical success and commercial potential. For research and development candidates in early stages of development, it is premature to estimate when material net cash inflows from these projects might occur.

General and Administrative Expenses

General and administrative expense consists primarily of salaries and related expenses for personnel in administrative, finance, business development and human resource functions, as well as the legal costs of pursuing patent protection of our intellectual property and patent filing and maintenance expenses, stock–based compensation, and professional fees for legal services. Our total general and administration expenses for the three months and six months ended June 30, 2021 were $4.5 million and $6.0 million, respectively, compared to $6.2 million and $10.3 million for the three months and six months ended June 30, 2020, respectively. Share-based compensation accounted for $0.5 million and $1.0 million for the three months and six months ended June 30, 2021, respectively, compared to $1.9 million and $4.0 million for the three months and six months ended June 30, 2020, respectively.

General and administrative expenses, as a percentage of total operating expenses for the three months and six months ended June 30, 2021 were 33% and 30%, respectively, compared to 71% and 73% for the three months and six months ended June 30, 2020, respectively. The percentages, excluding share-based compensation, for the three months and six months ended June 30, 2021 were 31% and 27%, respectively, compared to 76% for both the three months and six months ended June 30, 2020.

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, 2021 and 2020 are summarized as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Revenue				
Manufacturing revenue	$ 4,500	$ 4,500	$ 9,000	$ 7,500
Clinical Trial revenue	25	10,998	375	20,679
Total revenue	$ 4,525	$ 15,498	$ 9,375	$ 28,179

Under the clinical manufacturing agreement with Janssen, we have recorded $4.5 million as manufacturing for the three months ended June 30, 2021and 2020. Clinical trial revenue 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 $19 thousand pass-through revenue for two trials and $6 thousand mark-up revenue for the three months ended June 30, 2021 and $8.5 million pass through revenue and $2.5 million mark-up revenue for the three months ended June 30, 2020.

We have recorded $9.0 million manufacturing revenue for the six months ended June 30, 2021, compared to $7.5 million for the six months ended June 30, 2020. Clinical trial revenue for the six months ended June 30, 2021 is $0.4 million, including $0.3 million pass-through expense for two trials and $0.1 million mark-up revenue compared to $20.7 million for the six months ended June 30, 2020. The decrease of the clinical trial revenue in 2021 was due to the completion of the Janssen clinical trials on December 2020.

Cost of Goods Sold

Cost of goods sold during the three months and six months ended June 30, 2021 and 2020 are summarized as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	**2020**	**2021**	**2020**
Cost of goods sold				
Manufacturing cost	$ 1,341	$ 3,956	$ 3,376	$ 6,122
Clinical trial cost	19	9,245	288	16,753
Total cost of goods sold	$ 1,360	$ 13,201	$ 3,664	$ 22,875

The manufacturing cost for the three months end June 30, 2021 and 2020 represents period expense for manufacturing, quality assurance and quality control departments. Clinical trial cost for the three months end June 30, 2021 and 2020 is the pass-through expenses for two trials.

We have recorded $3.4 million manufacturing cost for the six months ended June 30, 2021, compared to $6.1 million for the six months ended June 30, 2020. Clinical trial cost for the six months ended June 30, 2021 is $0.3 million including the pass- through expenses for two trials and other related clinical trial department expenses, compared to $16.8 million for the six months ended June 30, 2020. The three months and six months decrease was mainly due to the completion of the Janssen clinical trials on December 2021.

Expenses

Research and Development

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

	Three Months Ended June 30,		Increase	% Increase
	2021	**2020**	**(Decrease)**	**(Decrease)**
Salaries and related expenses	$ 5,656	$ 354	$ 5,302	1498%
Laboratory and manufacturing supplies	1,137	136	1,001	736%
Clinical trials and sponsored research	450	594	(144)	-24%
Stock-based compensation	433	1,214	(781)	-64%
Other	1,578	267	1,312	491%
Total	$ 9,254	$ 2,565	$ 6,690	261%

	Six Months Ended June 30,		Increase	% Increase
	2021	**2020**	**(Decrease)**	**(Decrease)**
Salaries and related expenses	$ 7,212	$ 675	$ 6,537	968%
Laboratory and manufacturing supplies	2,018	261	1,757	673%
Clinical trials and sponsored research	774	594	180	30%
Stock-based compensation	796	1,747	(951)	-54%
Other	3,088	443	2,645	597%
Total	$ 13,888	$ 3,720	$ 10,168	273%

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

Research and development expenses increased 261% to $9.3 million for the three months ended June 30, 2021 compared to $2.6 million for the three months ended June 30, 2020. Research and development expenses also increased 273% to $13.9 million for the six months ended June 30, 2021 compared to $3.7 million for the six months ended June 30, 2020.

The three months and six months increase was mainly due to the reclassification of expense. A portion of manufacturing department expenses were reclassed to cost of goods sold in 2021 compared to all manufacturing department expensed being reclassed to cost of goods sold in 2020, as all such expense incurred in 2020 were related to the clinical trial manufacturing agreement in the Janssen Transaction. Salaries and related expenses increased because of the $7.0 million bonus to the Chief Executive Officer in June 2021, in which 60% was allocated to research and development expenses. Also, clinical trials expense in 2021 was generated from the commencement of a new phase I clinical trials for a new indication. The other expense in 2021 includes the facility allocation and other miscellaneous expense.

General and Administrative

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

	Three Months Ended June 30, 2021	2020	Increase (Decrease)	% Increase (Decrease)
Salaries and related expenses	$ 3,036	$ 2,979	$ 57	2%
Patent filing expense	132	131	1	1%
Stock-based compensation	534	1,872	(1,338)	-71%
Professional fees	350	641	(291)	-45%
Other	464	623	(159)	-26%
Total	$ 4,516	$ 6,246	$ (1,730)	-28%

	Six Months Ended June 30, 2021	2020	Increase (Decrease)	% Increase (Decrease)
Salaries and related expenses	$ 3,291	$ 3,237	$ 54	2%
Patent filing expense	268	270	(2)	-1%
Stock-based compensation	1,046	4,016	(2,970)	-74%
Professional fees	813	1,579	(766)	-49%
Other	563	1,167	(604)	-52%
Total	$ 5,981	$ 10,269	$ (4,288)	-42%

General and administrative expenses decreased to $4.5 million for the three months ended June 30, 2021 compared to $6.2 million for the three months ended June 30, 2020. General and administrative expenses decreased to $6.0 million for the six months ended June 30, 2021 compared to $10.3 million for the six months ended June 30, 2020.

The three months decrease was primarily related to stock–based compensation expenses of $1.7 million in 2020, due to the new grants to employees and Chief Executive Officer in the fourth quarter of 2019, which was fully amortized in 2021. Salaries and related expense increased due to the $7.0 million bonus to the Chief Executive Officer in June 2021, in which 40% was allocated to general and administrative expenses, compared to the $2.7 million bonus in June 2020, in which 70% was allocated to general and administrative expenses.

Compared to the six months ended June 30, 2020, the general and administrative expense decreased in the six months ended June 30, 2021 was primarily caused by the decrease to stock-based compensation expense. Also, professional fees decreased $0.8 million mainly due to our no longer requirement of 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 June 30,		Six Months Ended June 30,	
	2021	**2020**	**2021**	**2020**
Interest income	$ 123	$ 306	$ 232	$ 2,204
Other income (loss)	(2)	(503)	(11)	(503)
Foreign exchange gain (loss)	793	(465)	1,202	(558)
Total	$ 914	$ (662)	$ 1,423	$ 1,143

The interest income for the three months and six months ended June 30, 2021 and 2020 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, 2021 compared to 2020.

Liquidity and Capital Resources

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

Since our inception on March 22, 2005 through March 31, 2021, we have funded our operations principally through private placements and public offerings of equity securities, which have provided aggregate cash proceeds of approximately $308.6 million. We received $675 million in cash proceeds from the Janssen Transaction in the year ended December 31, 2019, and $4.5 million and $9.4 million revenue from the manufacturing agreement and clinical trial agreement for the three months and six months ended June 30, 2021, respectively. In June 2021, we received the remaining $75 million cash as the escrow receivable from the same transaction. During this year, we expect that the revenues from Janssen Transaction will generate enough cash for our research and development activities. At June 30, 2021, we had cash and cash equivalents of $315.3 million as compared to cash and cash equivalents of $229.7 million at June 30, 2020. The following table summarizes our sources and uses of cash (in thousands):

	Six Months Ended June 30,	
Net cash (used in) provided by:	**2021**	**2020**
Operating activities	$ 74,606	$ (72,241)
Investing activities	(2,349)	(815)
Financing activities	4,998	(411,804)
Effect of foreign exchange rate on cash and cash equivalents	637	(31)
Net change in cash and cash equivalents	$ 77,892	$ (484,891)

During the six months ended June 30, 2021, our operating activities generated net cash of $74.6 million and used net cash $72.2 million, respectively. The change in cash from operations for the six months ended June 30,2021 primarily resulted from the $75 million escrow received. The net cash used in operating activities for the six months ended June 30, 2020 was mainly due to the $51.1 million income tax payment for 2019.

During the six months ended June 30, 2021 and 2020, our investing activities used net cash of $2.3 million and $815 thousand, respectively. The use of cash was for building expansion and warehouse in construction.

During the six months ended June 30, 2021 and 2020, our financing activities provided net cash of $5.0 million and used net cash proceeds of $411.8 million, respectively. During the six months ended June 30, 2021, employees exercised stock options to purchase a total of 743 thousand shares of our common stock for approximately $5.1 million in net proceeds. 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 repurchase 14,000,000 common shares at a price of $30.00 per share, relating to the tender offer completed in February 2020.

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. Further, the clinical manufacturing agreement will expire on December 31, 2021, after which we do not expect to receive any additional revenue under that agreement. As of June 30, 2021, our principal sources of liquidity were our cash and cash equivalents, which totaled approximately $315.3 million.

Off-Balance Sheet Arrangements

Since inception, we have not engaged in any off-balance sheet activities, including the use of structured finance, special purpose entities or variable interest entities.

Item 3.Quantitative and Qualitative Disclosure 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, 2021 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, 2020. 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, 2020, which could materially affect our business, financial condition or future results. The risks described in our Annual Report on Form 10-K, as well as other risks and uncertainties, could materially and adversely affect our business, results of operations and financial condition, which in turn could materially and adversely affect the trading price of shares of our Common Stock. Additional risks not currently known or currently material to us may also harm our business.

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

Not Applicable.

Item 3. Defaults upon Senior Securities

Not Applicable.

Item 4. Mine Safety Disclosures

Not Applicable.

Item 5. Other Information.

Not Applicable.

Item 6. Exhibits.

31.1	Certification of Principal Executive Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.
31.2	Certification of Principal Financial Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.
32.1	Certification of Principal Executive Officer and Principal Financial Officer Required Under Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. §1350.
101	The following financial statements from the XBiotech Inc. Quarterly Report on Form 10-Q for the quarter ended June 30, 2021, 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 9, 2021

XBIOTECH INC.

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

Date: August 9, 2021

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

Exhibit 31.1

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 9, 2021

/S/ John Simard
John Simard
Chief Executive Officer and President
(Principal Executive Officer)

Exhibit 31.2

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 9, 2021

/S/ QUEENA HAN
Queena Han
Vice President, Finance and Human Resources and Secretary
(Principal Financial Officer)

Exhibit 32.1

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, 2021 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 9, 2021

In connection with the Quarterly Report of XBiotech Inc. on Form 10-Q for the period ended June 30, 2021, 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
Queena Han
Vice President, Finance and Human Resources and Secretary
(Principal Financial Officer)
Date: August 9, 2021