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 September 30, 2022

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 November 9, 2022, there were 30,439,277 shares of the Registrant's common stock issued and outstanding.

XBIOTECH INC.
THREE MONTHS AND NINE MONTHS ENDED SEPTEMBER 30, 2022
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CAUTIONARY STATEMENTS REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements, which reflect our current views with respect to, among other things, our operations and financial performance. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q are forward-looking statements. You can identify forward-looking statements by terminology such as "may," "will," "should," "would," "could," "expects," "plans," "contemplate," "anticipates," "believes," "estimates," "predicts," "projects," "intend" or "continue" or the negative of such terms or other comparable terminology, although not all forward-looking statements contain these identifying words. Forward-looking statements are subject to inherent risks and uncertainties in predicting future results and conditions that could cause the actual results to differ materially from those projected in these forward-looking statements. These forward-looking statements include, but are not limited to statements about:

- *our ability to obtain regulatory approval to market and sell 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 achieve profitability;*
- *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;*

- *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 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, 2021 filed with the SEC on March 15, 2022, 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.

Condensed Consolidated Balance Sheets
(in thousands, except share data)

	September 30, 2022 (Unaudited)	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 160,568	$ 236,983
Interest bearing time deposits	59,532	-
Account receivable	1,530	-
Income tax receivable	1,176	8,953
Prepaid expenses and other current assets	621	934
Total current assets	223,427	246,870
Property and equipment, net	26,635	28,307
Deferred tax assets	772	-
Total assets	$ 250,834	$ 275,177
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	$ 1,376	$ 2,069
Accrued expenses	1,988	1,374
Income tax payable	214	10
Total current liabilities	3,578	3,453
Long-term liabilities:		
Income tax payable	1,575	1,466
Deferred tax liability	872	873
Total liabilities	6,025	5,792
Shareholders' equity:		
Common stock and additional paid in capital, no par value, unlimited shares authorized, 30,439,277 shares outstanding at September 30, 2022 and December 31, 2021, respectively	266,287	262,263
Accumulated other comprehensive income	3,068	1,971
Accumulated (deficit) equity	(24,546)	5,151
Total shareholders' equity	244,809	269,385
Total liabilities and shareholders' equity	$ 250,834	$ 275,177

See accompanying notes to unaudited condensed consolidated financials statements.

XBiotech Inc.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022 (unaudited)	2021 (unaudited)	2022 (unaudited)	2021 (unaudited)
Revenue				
Manufacturing revenue	$ 1,680	$ 4,500	$ 3,710	$ 13,500
Clinical trial service revenue	-	19	-	394
Total revenue	1,680	4,519	3,710	13,894
Cost of goods sold				
Manufacturing cost	215	1,095	635	4,471
Clinical trial cost	-	15	-	303
Total cost of goods sold	215	1,110	635	4,774
Gross margin	1,465	3,409	3,075	9,120
Operating expenses:				
Research and development	7,014	5,599	24,227	19,486
General and administrative	840	1,541	5,176	7,522
Total operating expenses	7,854	7,140	29,403	27,008
Loss from operations	(6,389)	(3,731)	(26,328)	(17,888)
Other (loss) income:				
Interest income	1,009	125	1,351	357
Other expense	-	(121)	(119)	(132)
Foreign exchange (loss) gain	(4,877)	(1,328)	(5,867)	(127)
Total other (loss) income	(3,868)	(1,324)	(4,635)	98
Loss before income taxes	(10,257)	(5,055)	(30,963)	(17,790)
Income tax (expense) benefit	(2,401)	1,794	1,266	6,843
Net loss	$ (12,658)	$ (3,261)	$ (29,697)	$ (10,947)
Net loss per share—basic and diluted	$ (0.42)	$ (0.11)	$ (0.98)	$ (0.37)
Shares used to compute basic and diluted net loss per share	30,439,277	30,341,470	30,439,277	29,921,048

See accompanying notes to unaudited condensed consolidated financials statements.

XBiotech Inc.

Condensed Consolidated Statements of Comprehensive Loss (unaudited)
(in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022 (unaudited)	2021 (unaudited)	2022 (unaudited)	2021 (unaudited)
Net loss	$ (12,658)	$ (3,261)	$ (29,697)	$ (10,947)
Foreign currency translation adjustment	544	(240)	1,097	397
Comprehensive loss	$ (12,114)	$ (3,501)	$ (28,600)	$ (10,550)

See accompanying notes to unaudited condensed consolidated financials statements.

XBiotech Inc.

Condensed Consolidated Statements of Shareholders' Equity (unaudited)
(in thousands)

	Number of Shares	Common Stock and Additional Paid in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated (Deficit) Equity	Total
Balance at June 30, 2022	30,439	$ 265,159	$ 2,524	$ (11,888)	$ 255,795
Net loss	-	-	-	(12,658)	(12,658)
Foreign currency translation adjustment	-	-	544	-	544
Share-based compensation expense	-	1,128	-	-	1,128
Balance at September 30, 2022	30,439	$ 266,287	$ 3,068	$ (24,546)	$ 244,809

	Number of Shares	Common Stock and Additional Paid in Capital	Accumulated Other Comprehensive Income	Accumulated Equity (Deficit)	Total
Balance at June 30, 2021	30,024	$ 256,779	$ 1,903	$ 89,882	$ 348,564
Net loss	-	-	-	(3,261)	(3,261)
Foreign currency translation adjustment	-	-	(240)	-	(240)
Issuance of common stock under stock option plan	374	2,964	-	-	2,964
Dividends	-	-	-	(75,003)	(75,003)
Share-based compensation expense	-	1,133	-	-	1,133
Balance at September 30, 2021	30,398	$ 260,876	$ 1,663	$ 11,618	$ 274,157

	Number of Shares	Common Stock and Additional Paid in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated (Deficit) Equity	Total
Balance at December 31, 2021	30,439	$ 262,263	$ 1,971	$ 5,151	$ 269,385
Net loss	-	-	-	(29,697)	(29,697)
Foreign currency translation adjustment	-	-	1,097	-	1,097
Share-based compensation expense	-	4,024	-	-	4,024
Balance at September 30, 2022	30,439	$ 266,287	$ 3,068	$ (24,546)	$ 244,809

	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	-	-	-	(10,947)	(10,947)
Foreign currency translation adjustment	-	-	397	-	397
Issuance of common stock under stock option plan	1,094	7,962	-	-	7,962
Dividends	-	-	-	(75,003)	(75,003)
Share-based compensation expense	-	3,109	-	-	3,109
Balance at September 30, 2021	30,398	$ 260,876	$ 1,663	$ 11,618	$ 274,157

See accompanying notes to unaudited condensed consolidated financials statements.

XBiotech Inc.

Condensed Consolidated Statements of Cash Flows (unaudited)
(in thousands)

	Nine Months Ended September 30,	
	2022 (unaudited)	**2021 (unaudited)**
Operating activities		
Net loss	$ (29,697)	$ (10,947)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Depreciation	2,171	1,946
Share-based compensation expense	4,024	3,109
Changes in operating assets and liabilities:		
Account receivable	(1,530)	4,069
Income tax receivable	7,777	(3,823)
Deferred cost of goods sold	-	1,633
Escrow receivable	-	75,063
Prepaid expenses and other current assets	314	207
Deferred tax assets	(772)	(108)
Accounts payable	(741)	(1,679)
Accrued expenses	614	292
Income tax payable	314	1,334
Deferred tax liability	(1)	108
Net cash (used in) provided by operating activities	(17,527)	71,204
Investing activities		
Purchase of property and equipment	(453)	(3,049)
Purchase of interest bearing time deposits	(59,532)	-
Net cash used in investing activities	(59,985)	(3,049)
Financing activities		
Dividends	-	(75,003)
Issuance of common stock under stock option plan	-	7,962
Net cash used in financing activities	-	(67,041)
Effect of foreign exchange rate on cash and cash equivalents	1,097	397
Net change in cash and cash equivalents	(76,415)	1,511
Cash and cash equivalents, beginning of period	236,983	237,366
Cash and cash equivalents, end of period	$ 160,568	$ 238,877
Supplemental Information:		
Accrued purchases of property and equipment	46	202

See accompanying notes to unaudited condensed consolidated financial statements.

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. The Company has in its pipeline both anti-infective and anti-inflammatory candidate therapeutics derived from this technology.

An area of medical focus for XBiotech are therapies that block a potent substance naturally produced by the 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"). On February 2, 2022, XBiotech announced an addendum to the 2019 Janssen Manufacturing Agreement. XBiotech will continue to manufacture bermekimab for use by Janssen in its clinical trials through December 2023. 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 $160.6 million at September 30, 2022, will enable the Company to achieve several major inflection points, including potential new clinical studies with lead product candidates. The Company expects to have sufficient cash through 12 months from the date of this report.

2. Significant Accounting Policies

Basis of Presentation

The condensed consolidated balance sheet as of September 30, 2022, the condensed consolidated statements of operations and comprehensive loss and shareholders' equity for the three and nine months ended September 30, 2022 and 2021, and the condensed consolidated statement of cash flows for the nine months ended September 30, 2022 were prepared by management without audit. In the opinion of management, all adjustments, consisting only of normal recurring adjustments, except as otherwise disclosed, necessary for the fair presentation of the financial position, results of operations, and changes in financial position for such periods, have been made.

Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") have been condensed or omitted. These interim financial statements should be read in conjunction with the consolidated financial statements and notes thereto included in our Form 10-K for the year ended December 31, 2021. The results of operations for the period ended September 30, 2022 are not necessarily indicative of the operating results that may be expected for a full year. The condensed consolidated balance sheet as of December 31, 2021 contains financial information taken from the audited XBiotech Inc. consolidated financial statements as of that date.

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 the 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. The Company executed an addendum related to manufacturing agreement, which is expected to generate revenue through December 2023. While these agreements are not considered contracts with a customer based on the terms thereof, the Company is 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 Company 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. The Company only applies the five-step model to contracts (including by analogy) when it is probable that the Company will collect the consideration it is entitled to in exchange for the goods or services it transfers to the counterparty. At contract inception, once the contract is determined to be within the scope of or analogized to ASC 606, the Company assesses the goods or services promised within each contract and determine those that are performance obligations, and assesses whether each promised good or service is distinct. The Company then recognizes 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 the years ended 2020 and 2021. In 2022 the Company executed an addendum to the 2019 Janssen Manufacturing Agreement . The agreement is expected to generate as much as $4.7 million in revenue through December 2023.

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 who 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

The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the future tax consequences attributable to temporary differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. The Company measures deferred tax assets and liabilities using the enacted tax rates for the years and jurisdictions in which the temporary differences are expected to be recovered. A change to the tax rates used to measure the Company's deferred taxes is recognized in income during the period in which the new rate(s) were enacted.

The Company recognizes deferred tax assets to the extent the Company's assets are more likely than not to be realized. In making such a determination, the Company considers all available positive and negative evidence, including the future reversals of existing taxable temporary differences, projected future taxable income exclusive of reversing temporary differences and carryforwards, tax-planning strategies, taxable income in prior carryback years if permitted under tax law, and the results from prior years. If the Company determines it is more likely than not, that all or a portion of a deferred tax asset will not be realized a valuation allowance is recorded with a charge to income tax expense. Alternatively, if the Company determines that all or a portion of a deferred tax asset previously not meeting the more likely than not threshold will be realized, the Company reduces its valuation allowance and recognizes a benefit in income tax expense.

The Company recognizes and measure uncertain tax benefits in accordance with ASC 740 based on a two-step process in which (1) the Company determines whether it is more likely than not that the tax position will be sustained based on the technical merits of the position, and (2) for those tax positions that meet the more-likely-than-not recognition threshold, the Company recognizes the largest amount of tax benefit that is more than fifty percent likely to be realized upon ultimate settlement with the related tax authority. The Company's policy is to recognize interest and penalties related to uncertain tax positions, if any, in income 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 nine months ended September 30, 2022 and 2021 was included in the following line items on the Condensed Consolidated Statements of Operations (in thousands).

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Research and development	$ 855	$ 436	$ 2,824	$ 1,233
General and administrative	273	628	1,200	1,673
Cost of goods sold	-	69	-	203
Total share-based compensation expense	$ 1,128	$ 1,133	$ 4,024	$ 3,109

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 September 30,						Nine Months Ended September 30,					
	2022			2021			2022			2021		
Dividend yield		-			-			-			-	
Expected volatility		83%			84%	- 91%		82%	-	83%	84%	- 91%
Risk-free interest rate	2.9%	-	3.3%	0.9%	-	1.0%	1.5%	-	3.5%	0.5%	-	1.1%
Expected life (in years)		6.25			6.25			5.38	-	6.25	5.38	- 6.25
Weighted-average grant date fair value per share		3.71			16.17			4.93			16.69	

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 and Canadian banks. Cash and cash equivalents are stated at cost which approximates fair value.

Interest Bearing Time Deposit

The Company holds guaranteed investment certificates with a financial institution. The guaranteed investment certificates have a 12 month term at origination with interest payable at maturity.

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.

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 during the three and nine month periods ended September 30, 2022 and 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 loss per share ("EPS") is computed by dividing net loss by the weighted average number of common shares outstanding during each period. Diluted EPS is computed by dividing net loss by the weighted average number of common shares and common share equivalents outstanding (if dilutive) during each period. The number of common share equivalents, which include stock options, is computed using the treasury stock method.

Subsequent Events

The Company considered events or transactions occurring after the balance sheet date but prior to the date the consolidated financial statements are available to be issued for potential recognition or disclosure in its consolidated financial statements. We have evaluated subsequent events through the date of filing this Form 10-Q.

Recent Accounting Pronouncements

Recently Issued Accounting Pronouncements

In 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.

3. Revenue

On February 2, 2022, the Company announced an addendum to the 2019 Janssen Manufacturing Agreement XBiotech will continue to manufacture bermekimab for use by Janssen in its clinical trials through December 2023. For the three months and nine months ended September 30, 2022, the Company has recorded $1.7 and $3.7 million, respectively of gross revenue under the February 2022 agreement.

4. Property and Equipment

Property and equipment consisted of the following as of September 30, 2022 and December 31, 2021 (in thousands):

	September 30, 2022	December 31, 2021
Manufacturing equipment	$ 2,941	$ 3,796
Winnebago building	21,259	21,587
Other fixed assets	2,435	2,924
Total property and equipment	$ 26,635	$ 28,307

5. Common Stock

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

From January 1, 2021 through December 31, 2021, 1.1 million shares of common stock were issued upon the exercise of stock options at a price of $3.27 to $15.00 per share for total proceeds of $8.0 million.

No stock options were exercised from January 1, 2022 through September 30,2022.

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, 2021	4,656,677	$2.71	-	$21.74	$ 10.68
Granted	151,600	4.06	-	11.50	7.10
Exercised	-		-		-
Forfeitures	(137,650)	3.27	-	21.74	13.46
Options outstanding at September 30, 2022	4,670,627	$2.71	-	$21.74	$ 10.48

	Options	Exercise Price			Weighted-Average Exercise Price
Options outstanding at December 31, 2020	5,327,425	$2.71	-	$21.99	$ 6.09
Granted	162,000	$15.29	-	$20.20	16.69
Exercised	(1,093,415)	$3.27	-	$15.00	7.28
Forfeitures	(114,374)	$4.14	-	$21.99	9.75
Options outstanding at September 30, 2021	4,281,636	$2.71	-	$21.74	$ 10.36

As of September 30, 2022, there was approximately $4.0 million of unrecognized compensation cost, related to stock options granted under the Plans which will be amortized to stock compensation expense over the next 1.26 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 nine months ended September 30, 2022 and 2021 (in thousands, except share and per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Net loss	$ (12,658)	$ (3,261)	$ (29,697)	$ (10,947)
Weighted-average number of common shares—basic and diluted	30,439,277	30,341,470	30,439,277	29,921,048
Net loss per share—basic and diluted	$ (0.42)	$ (0.11)	$ (0.98)	$ (0.37)

Potentially dilutive securities outstanding, prior to the use of the treasury stock method or if-converted method, in the amount of 4,610,627 and 4,281,636 have been excluded from the computation of diluted weighted-average common shares outstanding as of September 30, 2022 and September 30, 2021, respectively, because including them would have had an anti-dilutive effect due to the losses reported.

8. Income Taxes

To calculate the interim tax provision, at the end of each interim period, the Company estimates the annual effective tax rate and applies that to its ordinary quarterly earnings. The effect of changes in the enacted tax laws or rates is recognized in the interim period in which the change occurs. The computation of the annual estimated effective tax rate at each interim period requires certain estimates and judgements including, but not limited to, the expected operating income for the year, permanent differences between book and tax amounts, and the likelihood of recovering deferred tax assets generated in the current year. The accounting estimates used to compute the provision for income taxes may change as new events occur, additional information is obtained, or the tax environment changes.

The Company's effective tax rates for the three months ended September 30, 2022 and September 30, 2021, were -23.4% and 35.5%, respectively. The effective tax rate for the three month period ended September 30, 2022 varied from the Canadian statutory rate primarily due to losses in jurisdictions for which a valuation allowance is recorded and no benefit is recognized and a shift in income between jurisdictions related to certain transfer pricing adjustments, which impacted the projected benefit associated with available loss carrybacks. The effective tax rate for the three month period ended September 30, 2021 varied from the Canadian statutory rate primarily due to non-deductible stock compensation, valuation allowances, and foreign inclusions.

The Company's effective tax rates for the nine months ended September 30, 2022 and September 30, 2021, were 4.1% and 38.5%, respectively. The effective tax rate for the nine month period ended September 30, 2022 varied from the Canadian statutory rate primarily due to losses in jurisdictions for which a valuation allowance is recorded and no benefit is recognized and a shift in income between jurisdictions related to certain transfer pricing adjustments, which impacted the projected benefit associated with available loss carrybacks. The effective tax rate for the nine month period ended September 30, 2021 varied from the Canadian statutory rate primarily due to non-deductible stock compensation, valuation allowances, and foreign inclusions.

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.

Following the Janssen Transaction in December 2019, the tender offer in February 2020, and the dividends paid in July 2021, the accumulated deficit as of September 30, 2022 was ($24.5) million. We had net losses before income tax of $10.3 million and $31.0 million for the three months and nine months ended September 30, 2022, respectively, compared to $5.1 million and $17.8 million for the three months and nine months ended September 30, 2021, respectively. During the next year, we expect the revenues from 2019 Janssen Transaction Addendum will be used in our research and development activities. 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. We will need to generate significant revenues to achieve or sustain profitability, and we may never do so. As of Septemeber 30, 2022, we had 93 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. In February 2022, we entered a new manufacturing contract with a Janssen-related company whereby we will continue to manufacture bermekimab through December 2023. The contract terminates in December 2023. 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.

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.

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 September 30, 2022, we have recorded total research and development expenses, including share-based compensation, of $271.8 million. Our total research and development expenses for the three months and nine months ended September 30, 2022 were $7.04 million and $24.2 million, respectively, compared to $5.6 million and $19.5 million for the three months and nine months ended September 30, 2021, respectively. Share-based compensation related to research and development was $0.9 million and $2.8 million for the three months and nine months ended September 30, 2022, respectively, compared to $0.4 million and $1.2 million for the three months and nine months ended September 30, 2021, respectively.

Research and development expenses, as a percentage of total operating expenses for the three months and nine months ended September 30, 2022 were 89% and 82%, respectively, compared to 78% and 72% for the three months and nine months ended Septmber 30, 2021, respectively. The percentages of research and development expenses compared to total operating expenses, excluding share-based compensation, for the three months and nine months ended September 30, 2022 were 92% and 84%, respectively, compared to 86% and 76% for the three months and nine months ended September 30, 2021.

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, maintenance expenses, share–based compensation, and professional fees for legal services. Our total general and administration expenses for the three months and nine months ended September 30, 2022 were $0.8 million and $5.2 million, respectively, compared to $1.5 million and $7.5 million for the three months and nine months ended September 30, 2021, respectively. Share-based compensation accounted for $0.3 million and $1.2 million for the three months and nine months ended September 30, 2022, respectively, and $0.6 million and $1.7 million for the three months and nine months ended September 30, 2021, respectively, related to general and administrative expenses.

General and administrative expenses, as a percentage of total operating expenses for the three months and nine months ended September 30, 2022 were 11% and 18%, respectively, compared to 22% and 28% for the three months and nine months ended September 30, 2021, respectively. The percentages of general and administrative expense compares to total operating expenses, excluding share-based compensation, for the three months and nine months ended September 30, 2022 were 8% and 16%, respectively, compared to 15% and 24% for the three months and nine months ended September 30, 2021.

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 in accordance with US GAAP requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and expenses incurred during the reporting 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 nine months ended September 30, 2022 and 2021 are summarized as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	**2021**	**2022**	**2021**
Revenue				
Manufacturing revenue	$ 1,680	$ 4,500	$ 3,710	$ 13,500
Clinical Trial revenue	-	19	-	394
Total revenue	$ 1,680	$ 4,519	$ 3,710	$ 13,894

Under the clinical manufacturing agreement with Janssen and the addendum, we have recorded $1.7 and $4.5 million as manufacturing revenue for the three months ended September 30, 2022 and 2021, respectively. 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 $15 thousand pass-through revenue for the two trials and $4 thousand mark-up revenue for the three months ended September 30, 2021. The clinical trial service agreement was terminated in the year 2022.

We have recorded $3.7 million in manufacturing revenue for the nine months ended September 30, 2022, compared to $13.5 million for the nine months ended September 30, 2021. Clinical trial revenue for the nine months ended September 30, 2021 was $0.4 million, which included $0.3 million in pass-through expense for two trials and a $0.1 million mark-up in revenue.

Cost of Goods Sold

Cost of goods sold during the three months and nine months ended September 30, 2022 and 2021 are summarized as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	**2021**	**2022**	**2021**
Cost of goods sold				
Manufacturing cost	$ 215	$ 1,095	$ 635	$ 4,471
Clinical trial cost	-	15	-	303
Total cost of goods sold	$ 215	$ 1,110	$ 635	$ 4,774

The manufacturing cost for the three months ended September 30, 2022 represents cost for the manufacuring department under the February 2022 agreement and the cost for the three months ended September 30, 2021 included expense for manufacturing, quality assurance, and quality control departments. Clinical trial cost for the three months ended September 30, 2021 is the pass-through expenses for two trials and other related clinical trial department expenses.

We have recorded $0.6 million in manufacturing cost for the nine months ended September 30, 2022, compared to $4.5 million for the nine months ended September 30, 2021. Clinical trial cost for the nine months ended September 30, 2021 was $0.3 million including the pass-through expenses for two trials and other related clinical trial department expenses. The three months and nine months decrease was mainly due to the completion of the Janssen clinical manufacturing agreement on December 2021 and the addendum signed in February 2022.

Expenses

Research and Development

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

	Three Months Ended September 30,		Increase	% Increase
	2022	**2021**	**(Decrease)**	**(Decrease)**
Salaries and related expenses	$ 2,086	$ 1,740	$ 346	20%
Laboratory and manufacturing supplies	1,817	1,251	566	45%
Clinical trials and sponsored research	349	158	191	121%
Share-based compensation	855	437	418	96%
Other	1,907	2,013	(106)	-5%
Total	$ 7,014	$ 5,599	$ 1,415	25%

	Nine Months Ended September 30,		Increase	% Increase
	2022	**2021**	**(Decrease)**	**(Decrease)**
Salaries and related expenses	$ 8,541	$ 8,952	$ (411)	-5%
Laboratory and manufacturing supplies	6,096	3,270	2,826	86%
Clinical trials and sponsored research	1,234	933	301	32%
Share-based compensation	2,824	1,233	1,591	129%
Other	5,532	5,098	434	8%
Total	$ 24,227	$ 19,486	$ 4,741	24%

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

Research and development expenses increased $1.4 million to $7.0 million for the three months ended September 30, 2022, compared to $5.6 million for the three months ended September 30, 2021. The increase was mainly due to the shift in operating activies as a result of the termination of the clinical trial manufacturing agreement in the Janssen Transaction. The increase of share-based compensation is due to the new grants to employees in the fourth quarter of 2021.

Research and development expenses increased $4.7 million to $24.2 million for the nine months ended September 30, 2022, compared to $19.5 million for the nine months ended September 30, 2021. The nine months increase was also mainly due to the shift in operating activities described above. Salaries and related expenses decreased because of the $3.8 million bonus to the Chief Executive Officer in June 2022 compared to the $7.0 million bonus in June 2021, in which 60% was allocated to research and development expenses for both periods. The other expense includes the facility allocation and other miscellaneous expense.

General and Administrative

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

	Three Months Ended September 30,		Increase	% Increase
	2022	**2021**	**(Decrease)**	**(Decrease)**
Salaries and related expenses	$ 260	$ 220	$ 40	18%
Patent filing expense	112	132	(20)	-15%
Share-based compensation	273	628	(355)	-57%
Professional fees	123	322	(199)	-62%
Other	72	239	(167)	-70%
Total	$ 840	$ 1,541	$ (701)	-45%

	Nine Months Ended September 30,		Increase	% Increase
	2022	**2021**	**(Decrease)**	**(Decrease)**
Salaries and related expenses	$ 2,259	$ 3,512	$ (1,253)	-36%
Patent filing expense	399	400	(1)	0%
Share-based compensation	1,200	1,673	(473)	-28%
Professional fees	642	1,135	(493)	-43%
Other	676	802	(126)	-16%
Total	$ 5,176	$ 7,522	$ (2,346)	-31%

General and administrative expenses decreased $0.7 million to $0.8 million for the three months ended September 30, 2022 compared to $1.5 million for the three months ended September 30, 2021. General and administrative expenses decreased $2.3 million to $5.2 million for the nine months ended September 30, 2022 compared to $7.5 million for the nine months ended September 30, 2021.

The three months decrease was primarily related to stock–based compensation expenses due to the fully amortized grants to employees in previous year. Professional fees also decreased $0.2 million due to the decrease in audit and tax service fees in 2022.

Compared to the nine months ended September 30, 2021, the general and administrative expense decrease in the nine months ended September 30, 2022 was primarily caused by the decrease in salaries and related expenses. The bonus to the Chief Executive Officer in June 2022 was $3.8 million compared to a $7.0 million bonus in June 2021, 40% of which was allocated to general and administrative expenses for both periods.
In addition, professional fees decreased $0.5 million mainly due to the decrease in annual audit fees in 2022.

Other income (loss)

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	**2021**	**2022**	**2021**
Interest income	$ 1,009	$ 125	$ 1,351	$ 357
Other loss	-	(121)	(119)	(132)
Foreign exchange loss	(4,877)	(1,328)	(5,867)	(127)
Total	$ (3,868)	$ (1,324)	$ (4,635)	$ 98

The interest income for the three months and nine months ended September 30, 2022 and 2021 was mainly generated from the Company's Canadian bank account. Foreign exchange loss was mainly due to the fluctuation between the US dollar and the Canadian dollar in the three months and nine months ended September 30, 2022 compared to 2021.

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 September 30, 2022, we have funded our operations principally through private placements and public offerings of equity securities, which have provided aggregate cash proceeds of approximately $118.2 million. We received $675 million in cash proceeds from the Janssen Transaction in the year ended December 31, 2019. In June 2021, we received the remaining $75 million in cash from the escrow receivable from the same transaction. In July 2021, we paid $75 million in dividends to shareholders. We expect that the revenues from Janssen Transaction Addendum will generate part of the cash for our research and development activities for one year following the date of these financial statements. At September 30, 2022, we had cash and cash equivalents of $160.6 million as compared to cash and cash equivalents of $238.9 million at September 30, 2021. The following table summarizes our sources and uses of cash (in thousands):

	Nine Months Ended September 30,	
Net cash (used in) provided by:	**2022**	**2021**
Operating activities	$ (17,527)	$ 71,204
Investing activities	(59,985)	(3,049)
Financing activities	-	(67,041)
Effect of foreign exchange rate on cash and cash equivalents	1,097	397
Net change in cash and cash equivalents	$ (76,415)	$ 1,511

During the nine months ended September 30, 2022 and 2021, our operating activities used net cash of $17.5 million and generated net cash $71.2 million, respectively. The cash from operations for the nine months ended September 30, 2021 primarily resulted from the $75 million escrow payment received from the Janssen Transaction.

During the nine months ended September 30, 2022 and 2021, our investing activities used net cash of $60.0 million and $3.0 million, respectively. In July 2022, we purchased interest bearing time deposits in the amount of $59.5 million. The use of cash in 2021 was for building expansion and warehouse in construction.

During the nine months ended September 30, 2021, our financing activities used net cash of $67.0 million. In July 2021, we paid $75 million in dividends to shareholders. During the nine months ended September 30, 2021, employees exercised stock options to purchase a total of 1.1 million shares of our common stock for approximately $8.0 million in net proceeds.

We expect to continue to incur operating losses in the future. Further, the clinical manufacturing agreement with Janssen expires on December 2023, after which we do not expect to receive any additional revenue under that agreement. As of September 30, 2022, our principal sources of liquidity were our cash and cash equivalents, which totaled approximately $160.6 million and $59.5 million interest bearing time deposits.

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 as amended. 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 September 30, 2022 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, 2021. 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, 2021, 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 September 30, 2022, formatted in Inline Extensive Business Reporting Language (XBRL): (i) condensed consolidated balance sheets at September 30, 2022 and December 31, 2021, (ii) condensed consolidated statements of operations for the three and nine months ended September 30, 2022 and 2021, (iii) condensed consolidated statements of comprehensive loss for the three and nine months ended September 30, 2022 and 2021, (iv))condensed consolidated statements of shareholders' equity for the three and nine months ended September 30, 2022 and 2021; (v) condensed consolidated statements of cash flows for the nine months ended September 30, 2022 and 2021 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: November 9, 2022

XBIOTECH INC.

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

Date: November 9, 2022

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.

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: November 9, 2022

/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.

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: November 9, 2022

/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 September 30, 2022 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: November 9, 2022

In connection with the Quarterly Report of XBiotech Inc. on Form 10-Q for the period ended September 30, 2022, 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: November 9, 2022