

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-Q**

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

For the quarterly period ended **March 31, 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

Non-accelerated filer

Accelerated filer

Smaller reporting company

Emerging growth company

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

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

As of May 10, 2022, there were 30,439,275 shares of the Registrant's common stock issued and outstanding.

**XBIOTECH INC.**  
**THREE MONTHS ENDED MARCH 31, 2022**  
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SIGNATURES

## 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.**

Consolidated Balance Sheets  
(in thousands, except share data)

	<b>March 31, 2022</b>		<b>December 31,</b>
	<b>(Unaudited)</b>		<b>2021</b>
<b>Assets</b>			
Current assets:			
Cash and cash equivalents	\$ 231,821	\$	236,983
Accounts receivable	500		-
Income tax receivable	10,027		8,953
Prepaid expenses and other current assets	632		934
<b>Total current assets</b>	<b>242,980</b>		<b>246,870</b>
Deferred tax asset	-		-
Property and equipment, net	27,823		28,307
<b>Total assets</b>	<b>\$ 270,803</b>	\$	<b>275,177</b>
<b>Liabilities and shareholders' equity</b>			
Current liabilities:			
Accounts payable	\$ 1,323	\$	2,069
Accrued expenses	1,568		1,374
Income tax payable	-		10
<b>Total current liabilities</b>	<b>2,891</b>		<b>3,453</b>
Long-term liabilities:			
Income tax payable	1,479		1,466
Deferred tax liability	873		873
<b>Total liabilities</b>	<b>5,243</b>		<b>5,792</b>
<b>Shareholders' equity:</b>			
Preferred Stock, no par value, unlimited shares authorized, no shares outstanding	-		-
Common stock and additional paid in capital, no par value, unlimited shares authorized, 30,439,275 shares outstanding at March 31, 2022 and December 31, 2021, respectively	263,711		262,263
Accumulated other comprehensive income	2,093		1,971
Accumulated equity and (deficit)	(244)		5,151
<b>Total shareholders' equity</b>	<b>265,560</b>		<b>269,385</b>
<b>Total liabilities and shareholders' equity</b>	<b>\$ 270,803</b>	\$	<b>275,177</b>

See accompanying notes.

**XBiotech Inc.**

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

	<b>Three Month Ended March 31,</b>	
	<b>2022</b>	<b>2021</b>
	<b>(unaudited)</b>	<b>(unaudited)</b>
<b>Revenue</b>		
Manufacturing revenue	\$ 500	\$ 4,500
Clinical trial service revenue	-	350
<b>Total revenue</b>	<u>500</u>	<u>4,850</u>
<b>Cost of goods sold</b>		
Manufacturing cost	213	2,035
Clinical trial cost	-	269
<b>Total cost of goods sold</b>	<u>213</u>	<u>2,304</u>
<b>Gross margin</b>	<u>287</u>	<u>2,546</u>
<b>Operating expenses:</b>		
Research and development	6,818	4,634
General and administrative	1,314	1,465
<b>Total operating expenses</b>	<u>8,132</u>	<u>6,099</u>
<b>Loss from operations</b>	<u>(7,845)</u>	<u>(3,553)</u>
<b>Other income (loss):</b>		
Interest income	101	109
Other expense	-	(10)
Foreign exchange gain (loss)	1,290	409
<b>Total other income</b>	<u>1,391</u>	<u>508</u>
<b>Loss before income taxes</b>	<u>(6,454)</u>	<u>(3,045)</u>
Provision/(benefit) for income taxes	(1,059)	(477)
<b>Net loss</b>	<u>\$ (5,395)</u>	<u>\$ (2,568)</u>
<b>Net loss per share—basic and diluted</b>	<u>\$ (0.18)</u>	<u>\$ (0.09)</u>
<b>Shares used to compute basic net loss per share</b>	30,043,380	29,423,727

*See accompanying notes.*

**XBiotech Inc.**

Consolidated Statements of Comprehensive Loss  
(in thousands)

	<b>Three Months Ended March 31,</b>	
	<b>2022</b>	<b>2021</b>
	<b>(unaudited)</b>	<b>(unaudited)</b>
Net loss	\$ (5,395)	\$ (2,568)
Foreign currency translation adjustment	122	319
Comprehensive loss	<u>\$ (5,273)</u>	<u>\$ (2,249)</u>

*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 (Loss)	Accumulated Equity (Deficit)	Total
Balance at December 31, 2021	30,439	262,263	1,971	5,151	\$ 269,385
Net loss	-	-	-	(5,395)	(5,395)
Foreign currency translation adjustment	-	-	122	-	122
Share-based compensation expense	-	1,448	-	-	1,448
Balance at March 31, 2022	30,439	\$ 263,711	\$ 2,093	\$ (244)	\$ 265,560

	Number of Shares	Common Stock and Additional Paid in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Equity	Total
Balance at December 31, 2020	29,304	249,805	1,266	97,568	\$ 348,639
Net loss	-	-	-	(2,568)	(2,568)
Foreign currency translation adjustment	-	-	319	-	319
Issuance of common stock under stock option plan	679	4,772	-	-	4,772
Share-based compensation expense	-	936	-	-	936
Balance at March 31, 2021	29,983	\$ 255,513	\$ 1,585	\$ 95,000	\$ 352,098

*See accompanying notes.*



**XBiotech Inc.**

Consolidated Statements of Cash Flows  
(in thousands)

	<b>Three Months Ended March 31,</b>	
	<b>2022</b>	<b>2021</b>
	<b>(unaudited)</b>	<b>(unaudited)</b>
<b>Operating activities</b>		
Net loss	\$ (5,395)	\$ (2,568)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation	710	621
Share-based compensation expense	1,448	936
Changes in operating assets and liabilities:		
Account receivable	(500)	2,425
Income tax receivable	(1,074)	3,225
Deferred cost of goods sold	-	544
Prepaid expenses and other current assets	302	(1,955)
Accounts payable	(812)	(1,409)
Accrued expenses	194	(10)
Deferred revenue	-	-
Income tax payable	4	-
Net cash provided by (used in) operating activities	(5,123)	1,809
<b>Investing activities</b>		
Purchase of property and equipment	(161)	(637)
Net cash used in investing activities	(161)	(637)
<b>Financing activities</b>		
Issuance of common stock under stock option plan	-	1,022
Net cash provided by (used in) financing activities	-	1,022
Effect of foreign exchange rate on cash and cash equivalents	122	319
Net change in cash and cash equivalents	(5,162)	2,513
Cash and cash equivalents, beginning of period	236,983	237,366
Cash and cash equivalents, end of period	\$ 231,821	\$ 239,879
<b>Supplemental information:</b>		
Accrued purchases of property and equipment	65	156

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. 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 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 \$231.8 million at March 31, 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

These consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States ("US GAAP"). In the opinion of management, the accompanying consolidated financial statements reflect all adjustments (consisting only of normal recurring items) considered necessary to present fairly the Company's financial position at March 31, 2022 and December 31, 2021, the shareholder's equity at March 31, 2022 and December 31, 2021, the results of its operations and comprehensive loss for the three month periods ended March 31, 2022 and 2021, and the cash flows for the three month periods ended March 31, 2022 and 2021.

### Basis of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All significant intercompany transactions have been eliminated upon consolidation.

### Use of Estimates

The preparation of financial statements in accordance with accounting principles generally accepted in the U.S. requires management to make estimates and assumptions that affect the reported values of amounts in the financial statements and accompanying notes. Actual results could differ from those estimates.

### Revenue

#### *Revenue from Janssen Agreements*

The Company recognizes revenues from its Janssen Agreements as follows.

The Company entered into its clinical manufacturing and clinical trial services arrangements in connection with its sale of certain intellectual property on December 30, 2019. These contracts commenced January 1, 2020. The Company executed a new related 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 year ended 2020 and 2021. In 2022 the Company executed a new manufacturing agreement with a Janssen related company. 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 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 ended March 31, 2022 and 2021 was included in the following line items on the Consolidated Statements of Operations (in thousands).

	Three Months Ended	
	March 31,	
	2022	2021
Research and development	\$ 990	\$ 363
General and administrative	458	512
Cost of goods sold	-	61
Total share-based compensation expense	\$ 1,448	\$ 936

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

	Three Months Ended	
	March 31,	
	2022	2021
Dividend yield	-	-
Expected volatility	82% - 83%	85% - 86%
Risk-free interest rate	1.5% - 2.4%	0.5% - 1.1%
Expected life (in years)	6.25	6.25
Weighted-average grant date fair value per share	\$7.14	\$13.82

### Cash and Cash Equivalents

The Company considers highly liquid investments with a maturity of three months or less when purchased to be cash equivalents. Cash and cash equivalents consisted primarily of cash on deposit in U.S., German, Swiss, Japanese and Canadian banks. Cash and cash equivalents are stated at cost which approximates fair value.

### Concentrations of Credit Risk

Financial instruments that potentially subject the Company to credit risk consist primarily of cash and cash equivalents. The Company holds these investments in highly-rated financial institutions, and limits the amounts of credit exposure to any one financial institution. These amounts at times may exceed federally insured limits. The Company has not experienced any credit losses in such accounts and does not believe it is exposed to any significant credit risk on these funds. The Company has no off-balance sheet concentrations of credit risk, such as foreign currency exchange contracts, option contracts or other hedging arrangements.

## Fair Value Measurements

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

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

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

At March 31, 2022 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 March 31, 2022 and December 31, 2021, 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 March 31, 2022.

## 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.

## 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 ended March 31, 2022, the Company has recorded \$0.5 million of revenues under the February 2022 agreement.

## 4. Property and Equipment

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

	March 31, 2022	December 31, 2021
Manufacturing equipment	\$ 3,497	\$ 3,796
Winnebago building	21,556	21,587
Other fixed assets	2,770	2,924
Total property and equipment	<u>\$ 27,823</u>	<u>\$ 28,307</u>

## 5. Common Stock

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

From January through December 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.

## 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	14,000	\$8.75 - \$11.25	9.99
Exercised	-	-	-
Forfeitures	(31,767)	\$10.36 - \$18.81	13.88
Options outstanding at March 31, 2022	4,638,910	\$2.71 - \$21.74	10.66

As of March 31, 2022, there was approximately \$6.8 million of unrecognized compensation cost, related to stock options granted under the Plans which will be amortized to stock compensation expense over the next 1.6 years.

## 7. Net Income/Loss Per Share

The following summarizes the computation of basic and diluted net income/loss per share for the quarter ended March 31, 2022 and 2021 (in thousands, except share and per share data):

	Three Months Ended March 31,	
	2022	2021
Net loss	\$ (5,395)	\$ (2,568)
Weighted-average number of common shares—basic and diluted	30,043,380	29,423,727
Net loss per share—basic and diluted	\$ (0.18)	\$ (0.09)

## 8. Income Taxes

During the three months ended March 31, 2021, the Company recorded an income tax benefit of \$477 thousand. During the three months ended March 31, 2022, the Company recorded an income tax benefit of \$1,059 thousand. The forecasted 2022 annual effective tax rate of 24.8% has been applied to Canadian income before income taxes for the three months ended March 31, 2022. The rate has not been applied against the US or Germany income before income taxes, as they are not expected to have a tax benefit or expense for the year in accordance with the exception provided in ASC 740-270-30-36. The consolidated effective tax rate for the three months ended March 31, 2022 was 16.41%, including amounts recorded for discrete events. The forecasted ETR disclosed here is misleading or indicates a significant discrete expense item (i.e. this amount times the \$6.5M YTD loss would indicate a higher YTD benefit). This is due to the US forecasted to be a full loss company with no benefit in the quarter and excluded from the estimated annual ETR. Please consider revising.

The difference in the 27% Canadian statutory tax rate and the annual forecasted effective tax rate is primarily a result of the jurisdictional mix of earnings and losses, valuation allowances, and permanently disallowed stock 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, 2021, there are \$2.4 million of unrecognized tax benefits recorded as a liability on the Company's financials. There was a \$14 thousand increase in the liability during the three months ended March 31, 2022 due to additional accrued interest on existing liabilities.

## 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, retained earnings as of March 31, 2022 were (\$0.2) million. We had net losses of \$5.4 million and \$2.6 million for the three months ended March 31, 2022 and 2021, respectively. During the next year, we expect the revenues from 2019 Janssen Transaction Addendum will generate offset operating expenses for 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. In addition to these increasing research and development expenses, we expect general and administrative costs to increase, particularly in consideration of current inflationary trends. We will need to generate significant revenues to achieve or sustain profitability, and we may never do so. As of December 31, 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. 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 operating expenses 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 March 31, 2022, we have recorded total research and development expenses, including share-based compensation, of \$254.4 million. Our total research and development expenses for the three months ended March 31, 2022 and 2021 were \$6.8 million and \$4.6 million, respectively. Share-based compensation accounted for \$990 thousand and \$363 thousand for the three months ended March 31, 2022 and 2021, respectively.

Research and development expenses, as a percentage of total operating expenses for the three months ended March 31, 2022 and 2021 were 84% and 76%, respectively. The percentages, excluding stock-based compensation, for the three months ended March 31, 2022 and 2021, were 87% and 82%, respectively.

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

#### General and Administrative Expenses

General and administrative expense consists primarily of salaries and related expenses for personnel in administrative, finance, business development and human resource functions, as well as the legal costs of pursuing patent protection of our intellectual property and patent filing and maintenance expenses, stock-based compensation, and professional fees for legal services. Our total general and administration expenses for the three months ended March 31, 2022 and 2021 were \$1.3 million and \$1.5 million, respectively. Share-based compensation accounted for both \$0.5 million for the three months ended March 31, 2022 and 2021, respectively.

General and administrative expense, as a percentage of total operating expenses for the three months ended March 31, 2022 and 2021 were 16% and 24%, respectively. The percentages, excluding stock-based compensation, for the three months ended March 31, 2022 and 2021, were 13% and 18%, respectively.



## 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, with the exception of certain Canada deferred tax assets that will reverse in a period in which they may be carried back, 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 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 March 31, 2022 and 2021 are summarized as follows (in thousands):

	Three Months Ended March 31,	
	2022	2021
Revenue		
Manufacturing revenue	\$ 500	\$ 4,500
Clinical Trial revenue	-	350
Total revenue	\$ 500	\$ 4,850

Under the clinical manufacturing agreement with Janssen and the addendum, we have recorded \$0.5 and 4.5 million as manufacturing revenue for the three months ended March 31, 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 \$269 thousand pass-through revenue for the two trials and \$81 thousand mark-up revenue for the three months ended March 31, 2021.

### Cost of Goods Sold

Cost of goods sold during the three months ended March 31, 2022 and 2021 are summarized as follows (in thousands):

	Three Months Ended March 31,	
	2022	2021
Cost of goods sold		
Manufacturing cost	\$ 213	\$ 2,035
Clinical trial cost	-	269
Total cost of goods sold	\$ 213	\$ 2,304

The manufacturing cost for the three months end March 31, 2022 represents cost for quality control department under February 2022 agreement and the cost for the three month end March 31, 2021 included period expense for manufacturing, quality assurance and quality control departments. Clinical trial cost for the three months end March 31, 2021 is the pass-through expenses for two trials and other related clinical trial department expenses.

## Expenses

### Research and Development

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

	Three Months Ended March 31,		Increase (Decrease)	% Increase (Decrease)
	2022	2021		
Salaries and related expenses	\$ 2,127	\$ 1,556	\$ 571	37%
Laboratory and manufacturing supplies	1,701	882	819	93%
Clinical trials and sponsored research	382	325	57	18%
Stock-based compensation	990	363	627	173%
Other	1,618	1,508	110	7%
Total	\$ 6,818	\$ 4,634	\$ 2,184	47%

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 \$2.2 million to \$6.8 million for the three months ended March 31, 2022, compared to \$4.6 million for the three months ended March 31, 2021. The increase was mainly due to the reclassification of expense. Manufacturing department expenses were not reclassified to cost of goods sold in 2021 compared to a portion of manufacturing department expenses were reclassified to cost of goods sold in 2021 as such expense incurred in 2021 were related to 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.

### General and Administrative

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

	Three Months Ended March 31,		Increase (Decrease)	% Increase (Decrease)
	2022	2021		
Salaries and related expenses	\$ 252	\$ 256	\$ (4)	-2%
Patent filing expense	146	136	10	7%
Stock-based compensation	458	512	(54)	-11%
Professional fees	293	463	(170)	-37%
Other	165	98	67	68%
Total	\$ 1,314	\$ 1,465	\$ (151)	-10%

General and administrative expense decreased \$0.2 million to \$1.3 million for the three months ended March 31, 2022, compared to \$1.5 million for the three months ended March 31, 2021. Professional fees decreased \$0.2 million mainly due to annual auditing fee for the year 2020 in the three months ended March 31, 2021 is higher for more overruns.

### Other income (loss)

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

	Three Months Ended March 31,	
	2022	2021
Interest income	\$ 101	\$ 109
Other income	-	(10)
Foreign exchange gain (loss)	1,290	409
Total	\$ 1,391	\$ 508

The interest income for the three months ended March 31, 2022 and 2021 was mainly from the interest generated from the Company's Canadian bank account. Foreign exchange gain and loss was mainly due to the fluctuation between the US dollar and the Canadian dollar in the three months ended March 31, 2022 compared to the three months ended March 31, 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 March 31, 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 cash as the escrow receivable from the same transaction. In July 2021, we paid \$75 million in dividends to shareholders. During the following 12 months, we expect that the revenues from Janssen Transaction Addendum will generate part of the cash for our research and development activities. At March 31, 2022, we had cash and cash equivalents of \$231.8 million as compared to cash and cash equivalents of \$239.9 million at March 31, 2021. The following table summarizes our sources and uses of cash (in thousands):

Net cash (used in) provided by:	Three Months Ended March 31,	
	2022	2021
Operating activities	\$ (5,123)	\$ 1,809
Investing activities	(161)	(637)
Financing activities	-	1,022
Effect of foreign exchange rate on cash and cash equivalents	122	319
Net change in cash and cash equivalents	\$ (5,162)	\$ 2,513

During the three months ended March 31, 2022 and 2021, our operating activities used net cash \$5.1 million and generated net cash \$1.8 million, respectively. The change in cash from operations for the three months ended March 31, 2022 as compared to the three months ended March 31, 2021 was mainly due to the Janssen revenue in 2021.

During the three months ended March 31, 2022 and 2021, our investing activities used net cash of \$161 thousand and \$637 thousand, respectively. The increase was due to costs incurred on the construction of the building extension and warehouse.

During the three months ended March 31, 2021, our financing activities provided net cash of \$1.0 million. Employees exercised stock options to purchase a total of 0.7 million shares of our common stock for approximately \$1.0 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 March 31, 2022, our principal sources of liquidity were our cash and cash equivalents, which totaled approximately \$231.8 million.

#### Off-Balance Sheet Arrangements

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

#### Item 3. Quantitative and Qualitative Disclosure of Market Risks

The Company is not currently exposed to material market risk arising from financial instruments, changes in interest rates or commodity prices, or fluctuations in foreign currencies. The Company has no need to hedge against any of the foregoing risks and therefore currently engages in no hedging activities.

#### Item 4. Controls and Procedures

##### Management's Evaluation of our Disclosure Controls and Procedures

As of the end of the year covered by this Annual 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.

##### Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act). We conducted an assessment of the effectiveness of our internal control over financial reporting based on the criteria set forth in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework). Based on our assessment, we have concluded that our internal control over financial reporting was effective as of December 31, 2021, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with GAAP.

**Changes in Internal Control Over Financial Reporting**

There was no change in our internal control over financial reporting that occurred during the quarter ended March 31, 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.

- |                             |   |
|-----------------------------|---|
| <a href="#"><u>31.1</u></a> | <a href="#"><u>Certification of Principal Executive Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.</u></a>   |
| <a href="#"><u>31.2</u></a> | <a href="#"><u>Certification of Principal Financial Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.</u></a>   |
| <a href="#"><u>32.1</u></a> | <a href="#"><u>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.</u></a>  |
| 101                         | The following financial statements from the XBiotech Inc. Quarterly Report on Form 10-Q for the quarter ended March 31, 2022, formatted in Inline Extensive 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: May 10, 2022

### **XBIOTECH INC.**

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

Date: May 10, 2022

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

## CERTIFICATIONS

I, John Simard, certify that:

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

Date: May 10, 2022

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

## CERTIFICATIONS

I, Queena Han, certify that:

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

Date: May 10, 2022

**/S/ QUEENA HAN**

Queena Han

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



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

In connection with the Quarterly Report of XBiotech Inc. on Form 10-Q for the period ended March 31, 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: May 10, 2022

In connection with the Quarterly Report of XBiotech Inc. on Form 10-Q for the period ended March 31, 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: May 10, 2022