UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2023
☐ Transaction 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 its charter)

British Columbia, Canada	**N/A**
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)

5217 Winnebago Ln, Austin, TX 78744
(Address of principal executive offices, including 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

Securities registered pursuant to Section 12(g) of the Act:
None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of June 30, 2023, was approximately $140,476,818, based upon the closing sales price for the registrant's common stock, as reported on the NASDAQ Global Market. The calculation of the aggregate market value of voting and non-voting common equity excludes 6,787,668 shares of common stock the registrant held by executive officers, directors and shareholders that the registrant concluded were affiliates of the registrant on that date. Exclusion of such shares should not be construed to indicate that any such person possesses the power, direct or indirect, to direct or cause the direction of management or policies of the registrant or that such person is controlled by or under common control with the registrant.

As of March 15, 2024, 30,450,881 shares of the registrant's Common Stock were outstanding.

Documents incorporated by reference:

Certain portions, as expressly described in this Annual Report on Form 10-K, of the registrant's Proxy Statement for the 2024 Annual Meeting of the Stockholders, to be filed not later than 120 days after the end of the year covered by this Annual Report, are incorporated by reference into Part III of this Annual Report where indicated.

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CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This annual report contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and is subject to the safe harbor created by those sections. All statements, other than statements of historical facts, included in this annual report, including, without limitation, statements regarding the assumptions we make about our business and economic model, our dividend policy, business strategy and other plans and objectives for our future operations, are forward-looking statements for purposes of federal and state securities laws.

Forward-looking statements involve risks and uncertainties, such as statements about our plans, objectives, expectations, assumptions or future events. In some cases, 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 denoting uncertainty or an action that may, will or is expected to occur in the future, 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. Some, but not all, examples of the forward-looking statements contained in this annual report include, among other things, statements about the following:

- *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.*

The ultimate correctness of these forward-looking statements depends upon a number of known and unknown risks and events. When reviewing the discussion below, you should keep in mind the substantial risks and uncertainties that impact our business. In particular, we encourage you to review the risks and uncertainties described in the "Risk Factors" and the other cautionary statements made in this annual report in our other SEC filings as being applicable to all related forward-looking statements wherever they appear in this annual report. We cannot assure you that the forward-looking statements in this annual report will prove to be accurate and therefore you are encouraged not to place undue reliance on forward-looking statements. You should read this annual report completely.

The forward-looking statements speak only as of the date on which they are made, and, except as required by law, we undertake no obligation to update any forward-looking statement to reflect events or circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. Nonetheless, we reserve the right to make such updates from time to time by press release, periodic report, or other method of public disclosure without the need for specific reference to this Quarterly Report. No such update shall be deemed to indicate that other statements not addressed by such update is incorrect or create an obligation to provide any other updates.

The information included in this Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with our audited consolidated financial statements and notes contained in this annual report.

PART I

ITEM 1. BUSINESS

Overview

XBiotech Inc. (“XBiotech” or the “Company”) is a biopharmaceutical company that discovers and develops True Human™ monoclonal antibodies for treating a variety of diseases. XBiotech was incorporated in Canada on March 22, 2005. The Company’s Internet address is www.xbiotech.com. The Company makes available free of charge on or through its website its annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as well as proxy statements, as soon as reasonably practicable after the Company electronically files such material with, or furnishes it to, the Securities and Exchange Commission. The Company’s website is included in this annual report on Form 10-K as an inactive textual reference only. The information on, or accessible through, the Company’s website is not a part of, or incorporated by reference in, this annual report on Form 10-K. The SEC maintains an Internet site that contains these reports at http://www.sec.gov.

XBiotech’s True Human™ monoclonal antibodies are derived from human donors that mount a natural human immune response. All other marketed antibody therapeutics are derived from animal immunization. It is intuitive that naturally occurring human antibodies have the potential to be safer, more effective and faster to develop than animal engineered counterparts. XBiotech has developed a pipeline of product candidates targeting both inflammatory and infectious diseases. The Company has also developed manufacturing technology that reduces the cost and time to launch new product candidates. The Company designed and built a state-of-the-art physical plant and infrastructure to discover manufacture and manage clinical trial operations for its therapeutic antibodies at its Company’s 48 acre research campus in Austin, Texas. XBiotech is thus a fully integrated developer of biopharmaceuticals.

An area of medical focus for XBiotech are therapies that block a potent substance, known as interleukin-1 alpha (IL-1a), that mediates a number of pathophysiological processes including tissue breakdown (ie. synovium, cartilage, bone), paraneoplastic angiogenesis and tumor stroma remodeling, formation of blood clots, malaise, muscle wasting and general 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 many chronic (eg. arthritis) and acute injury scenarios (eg. stroke), IL-1a may mediate harmful disease-related activity.

At the end of 2019, XBiotech sold a True Human™ antibody therapeutic it was developing that targeted IL-1a for $1.35 billion in cash and potential milestone payments. With the unique deal structure XBiotech agreed to not develop any anti-IL-1a antibodies for dermatology, while XBiotech remained free to continue to discover and develop new True Human™ anti-IL-1a antibodies for use in areas of medicine outside of dermatology. The Company quickly identified new IL-1a targeting product candidates that it is has already brought into clinical studies in oncology, rheumatology and neurology. While the Company previously was focused on a single True Human™ antibody targeting IL-1a, it is now developing in parallel two anti-IL-1a product candidates and may develop one or more others. Since IL-1a is involved in the pathology of multiple diseases, it makes business sense to use different anti-IL-1a antibodies for specific areas of medicine, allowing potential partnership or sale of each antibody separately for different disease indications.

Financial

XBiotech's sale of its True Human™ antibody Bermekimab generated a total $750 million in income between December 30, 2019 and June 30, 2021. Since 2020, the Company has returned a total of $495 million to its shareholders through a combination of stock repurchase and dividends. The remaining cash is being used for ongoing operations as part of a multi-year business plan to identify and commercialize True Human™ antibodies, including new anti-Il-1a therapies.

Starting in 2020, XBiotech used its proprietary manufacturing technology, its manufacturing plant and infrastructure to produce drug product under a supply agreement for a world-leading pharmaceutical company. In addition, during 2020 and 2021 XBiotech provided clinical trial operations services for two Phase II clinical studies for the same drug company. In 2022 XBiotech extended the supply agreement. As of March 2024, these agreements have now come to a successful conclusion and as of March 2024 XBiotech is no longer producing drug product or conducting contract clinical research.

Development of IL-1a Therapies

IL-1a is a substance produced by the body that plays a key role in many disease processes. While it is naturally made by the body, when not properly controlled, and in situations of acute or chronic injury, IL-1a can contribute to the development and progression of a variety of medical conditions, such as cancer, stroke, heart attack or arthritis, to name a few. Completed clinical studies and myriad scientific research has shown that blocking IL-1a may have a beneficial effect in many medical conditions. The potential unmet medical need for blocking IL-1a is therefore very significant, on the scale of the anti-TNF therapies developed over the past twenty-five years.

In 2021, the Company commenced a clinical study with its Natrunix™ True Human antibody targeting IL-1α in oncology (Pancreatic Cancer). The study is randomized, placebo controlled to provide a preliminary assessment of efficacy and safety for Natrunix in combination with chemotherapy in an advanced cancer population. The study was sized to include 60 subjects, intended to provide a preliminary assessment of efficacy. The last subject in the study had their last visit in February 2024. Data collection is therefore now complete. Over approximately the next six weeks, clinical monitors will perform visitations across the United States at clinical sites that enrolled subjects into the study. During these visits monitors will review source data to make sure all data has been properly recorded and upon satisfactory completion of the review, sites will be officially closed. When this process is complete, the database will be locked and data analyzed according to protocol. Reporting on results for the pancreatic cancer study are expected within several weeks of data lock.

The Company started a clinical program in Rheumatology in August, 2023 with a 210 patient study in rheumatoid arthritis. This double blind, placebo controlled study is investigating the efficacy of Natrunix as a treatment for rheumatoid arthritis in combination with the common prescription medication methotrexate. As of March 2024, the study has enrolled in about half of the subjects, with at least six months remaining until the last subject is taken into the program. The study aims to demonstrate that Natrunix will not only significantly enhance treatment outcomes of subjects already taking methotrexate, but that Natrunix will also reduce some of the side effects associated with Methotrexate. The Company is planning to launch additional studies in rheumatology during Q2 2024.

XBiotech filed an investigational new drug application in 2022 for our True Human™ antibody Hutrukin. Hutrukin is a candidate breakthrough therapeutic that is being evaluated for its ability to reduce brain injury that occurs after reperfusion procedures used to treat stroke. The company completed a phase I study at the end of 2023 that demonstrated high bolus doses of Hutrukin, similar to doses that would be given to prevent brain reperfusion injury in stroke therapy, are safe and well tolerated. Analysis of the data from the Phase I study is expected to be completed in Q1 2024. However, no significant adverse events were noted during the study and the data analysis is expected to be positive. The Company is planning a Phase II study in stroke during 2024. Ischemic stroke which accounts for some 87% of strokes, is a leading cause of mortality and serious long-term disability worldwide. For decades the medical approach has been to unblock the affected artery and return blood supply to the brain. It was intuitive that opening the occluded artery to return blood supply, or “reperfuse” the ischemic brain would lead to better outcomes for stroke victims. This expectation was not in fact supported by clinical observations.

Clinical studies have shown that in reality, reperfusion of the affected brain is associated with ongoing irreparable damage to ischemic tissue that, prior to reperfusion, appears viable by both physical and metabolic assessments. The necrotic infarct core that results from a stroke has been found to increase in size upon reperfusion, seemingly as a result of the resumption of enhanced blood supply.

Hutrukin may reduce the likelihood of inflammation-related secondary injury after ischemia by disrupting the molecular pathways which activate leukocyte migration and infiltration. Leukocyte migration and infiltration into the ischemic regions of the brain after reperfusion may mediate damage seen after reperfusion. Clinical studies with Hutrukin will be aimed at demonstrating a reduction of reperfusion injury and improved outcomes in stroke victims.

Infectious Disease Pipeline

While market potential keeps XBiotech focused on anti-IL-1a therapies, unmet medical need and the potential for uniquely effective product candidates keeps the Company dedicated to advancing its infectious disease pipeline. The Company has identified several major areas of urgent unmet medical need for True Human™ anti-infective antibody therapies. Human antibodies protect all of us on a daily basis from infectious disease—and the Company is highly confident that its True Human™ analogues of naturally immunity will serve as an extremely effective means for supplementing infectious immunity—in compromised individuals—against numerous related infectious diseases, such as shingles, influenza and C. difficile. The XBiotech discovery process involves procuring donations from blood banks and screening blood samples from healthy donors for antibodies that exhibit exceptionally strong immunity to specific diseases. True Human™ antibodies are derived only from donors who we have found to have the best disease fighting antibodies in that populations.

True Human™ antibodies may be used to provide highly potent and targeted immunity against infectious diseases, including: in the elderly, where natural immunity is waning; in young children where immunity has yet to develop; or even in otherwise healthy individuals, where infectious agents have overwhelmed natural immunity and where specially selected antibodies are needed to neutralize the infection (ie. staph aureus). For the latter population, this can occur during intravenous drug use, from a deep puncture wound, or from the result of surgery, where bacteria have gained unnatural entry into a body compartment where it can establish and evade the immune system.

The Company currently has a clinical stage therapeutic for methicillin resistant Staphylococcus aureus (MRSA), and several pre-clinical stage therapeutics, including: an oral delivery antibody therapeutic for colon infection by C. difficile; an injectable therapy for varicella zoster (aka adult chicken pox), the causative agent for shingles; and an influenza therapy, designed to neutralize all known strains and variants of influenza that have been identified since the 1918 pandemic.

Infrastructure

In 2022 XBiotech completed an expansion of its manufacturing and R&D center. The expansion resulted in the creation of two new wings: one provides state-of-the-art research laboratory for scientists; another area provides administrative space for dozens of personnel working in manufacturing, clinical and other operations. The building additions have enhanced the Company's ability to house a larger workforce, expand R&D activities and orchestrate the production of multiple drug products from its existing manufacturing and R&D center.

In Q1 2024 the Company re-launched its program to construct a new multi-story 46,000 ft^2 research and development facility and a 5,000 ft^2 infectious disease research annex, to further enhance the Company's discovery and product development capabilities. Both the multi-story complex and research annex will be located on the Company's 48 acre campus adjacent to the existing R&D center.

A Background on Therapeutic Antibodies

While antibody therapeutics have dominated drug development for the past 25 years, Kohler and Milstein probably never envisaged how difficult it would be to isolate and produce actual human antibodies. Today, in the $247 billion antibody market — apart from XBiotech's True Human™ antibodies — there is not a single antibody therapy derived from a natural human immune response: all are mouse derived and engineered, even those antibody therapies marketed as "human". John Simard, founder and CEO of XBiotech, recognized the potential to deliver a new generation of True Human™ antibodies and founded XBiotech around the mission to develop the technology to isolate and clone individual antibodies from human blood samples. Today, XBiotech has identified and produced numerous True Human™ antibodies candidate therapeutics that are derived from naturally immune individuals. XBiotech believes the greatest repository of medicines lies within the natural immune repertoire of the human body. The Company continues to catalogue and develop these True Human™ antibodies, which it sees as the greatest untapped resource for a new generation of therapeutics.

Employees and Human Capital

Each member of our senior management team has been with XBiotech on average for more than 12 years, and each has been with the Company through the process of antibody discovery, preclinical development, formulation, manufacturing, regulatory submissions, human clinical trials and commercial sale. Our employees' collective knowledge of our business allows us to operate as among the most cost effective, efficient and capable operations in the biotechnology industry. Our board of directors ("Board") is constituted by individuals with significant industry, scientific and legal knowledge. As of December 31, 2023, we had 82 full-time employees. None of our employees are represented by a collective bargaining agreement, nor have we experienced any work stoppage. We believe that our relations with our employees are good.

We are committed to growing our business over the long term. As a result of the competitive nature of the industry in which we operate, employees have significant career mobility and as a result, the competition for experienced employees is great. The existence of this competition, and the need for talented and experienced employees to realize our business objectives, underlies the design and implementation of our compensation programs. At the same time, we seek to keep our approach to compensation simple and streamlined to reflect the still relatively moderate size of our company. We have compensation, leave and benefits programs necessary to attract and retain the talented and experienced employees necessary to develop our business including competitive salaries, stock options awards to permanent employees, both upon initial hiring and annually thereafter, and pay annual bonuses to permanent employees contingent on the achievement of corporate and/or personal objectives. We have developed an Employee Handbook that contains all corporate policies and guidelines for professional behavior. Our policies and practices apply to all employees, regardless of title. These guidelines include our Code of Business Conduct and Ethics which is posted on our website.

ITEM 1A. RISK FACTORS

Summary

The following summarizes some of the key risks and uncertainties that could materially adversely affect us. You should read this summary together with the more detailed description of each risk factor contained below.

Risks Related to our Business, Financial Condition and Capital Requirements

- We will incur significant losses during development of our current pipeline over the foreseeable future.
- We currently have limited opportunities to generate revenue and may never sustain profitability.
- Our future success may be dependent on the regulatory approval and commercialization of our product candidates.
- New laws or regulations could impact our ability to receive the necessary approvals to successfully market and commercialize our product candidates.
- Product candidates we advance into clinical trials may not have favorable results in clinical trials or receive regulatory approval.
- For various reasons, we may be unable to complete clinical trials on a timely basis, incurring higher costs and delayed development timelines.
- The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable.

- Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences prior to or following any marketing approval.
- Any product candidates that we commercialize may not receive coverage and adequate reimbursement from third-party payers.
- If we are unable to establish an effective sales force and marketing infrastructure or enter into acceptable third-party sales and marketing or licensing arrangements, we may be unable to create optimal revenue from FDA approved products.
- Approved product candidates may not achieve adequate market acceptance for commercial success.
- We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.
- Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.
- Crucial components used in our manufacturing process are acquired from vendors. There are few alternate sources of these components, and ongoing supply could be disrupted.
- We are highly dependent on our Chief Executive Officer.
- We depend on key personnel to operate our business, and we may be unable to retain, attract and integrate qualified personnel.
- Failure to comply with environmental, health and safety laws and regulations could subject us to fines, penalties or other costs.
- Our business may be disrupted by natural disasters, infrastructure interruptions, or other public health threats.

Risks Related to Intellectual Property

- We may be unable to obtain or protect certain intellectual property rights.
- Intellectual property rights do not necessarily address all potential threats to any competitive advantage we may have.
- Our technology may be found to infringe upon third-party intellectual property rights.
- We may be unable to license needed intellectual property from third parties on commercially reasonable terms or at all, including intellectual property we in-license for manufacturing.
- If we are unable to protect the confidentiality of our trade secrets, our business and competitive position may be harmed.

Risks Related to Owning Shares of our Common Stock

- Our share price may be volatile, which could subject us to securities class action lawsuits and prevent you from being able to sell your shares at or above the price at which you purchased them.
- Our directors, executive officers and principal shareholders continue to have substantial control over our company and could hinder appropriate corporate control.
- Provisions in our charter documents under Canadian law could make an acquisition of us, which may be beneficial to our shareholders, more difficult.

- Against the judgment of the Company, we may be considered a passive foreign investment company for US tax purposes which may negatively affect US investors.

- We are governed by the corporate laws in British Columbia, Canada which in some cases have a different effect on shareholders than the corporate laws in Delaware.

General Risk Factors

- Raising additional capital may cause dilution to our existing shareholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

- Future sales, or the possibility of future sales, of a substantial number of our common stock could adversely affect the price of the shares and dilute shareholders.

- Any inability to accurately report our financial results or prevent fraud due to a failure to maintain effective internal control over financial reporting could cause shareholders to lose confidence in our financial and other public reporting.

Risks Related to our Business, Financial Condition and Capital Requirements

We have incurred significant losses since our inception and may incur significant losses in the future.

We are a pre-market pharmaceutical company with a limited operating history. We had no net income prior to the fourth quarter of 2019, when we sold certain assets to Janssen Biotech, Inc. and entered into certain related commercial agreements (the "Janssen Transaction"). Investment in pharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval or become commercially viable. We do not have any products approved by regulatory authorities for marketing or commercial sale and have not generated any revenue from product sales to date, and we continue to incur significant research, development and other expenses related to our ongoing operations. As a result, we incurred losses in every reporting period from our inception in 2005 through the third quarter of 2019. Although we were profitable during the fourth quarter and fiscal year ended December 31, 2019, due to the cash received in the Janssen Transaction, that was an extraordinary transaction outside of normal business operations that had never previously occurred and may not be repeated. We incurred a net loss for the fiscal year ended December 31, 2023.

We expect to continue to incur significant expenses and may incur operating losses for the foreseeable future. We anticipate these expenses will increase as we continue the research and development of and seek regulatory approvals for our current and future product candidates in various indications, and potentially begin to commercialize any products that may achieve regulatory approval. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our financial condition. The amount of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues. Our prior losses have had, and any future losses may continue to have, an adverse effect on our financial condition. If any of our product candidates fail in clinical trials or do not gain regulatory approval, or if approved fails to achieve market acceptance, we may never sustain profitability.

Since inception, we have dedicated the vast majority of our resources to the discovery and development of our proprietary preclinical and clinical product candidates, and we expect to continue to similarly expend substantial resources for the foreseeable future. These expenditures will include costs associated with conducting research and development, manufacturing product candidates, conducting preclinical experiments and clinical trials and obtaining and maintaining regulatory approvals, as well as commercializing any products later approved for sale. During the year ended December 31, 2023, we recognized approximately $32.8 million in expenses associated with research and development.

We completed our initial public offering on April 15, 2015 and additional registered offerings in March 2017 and May 2019. We also received a significant amount of cash proceeds from the sale of Bermekimab. However, the net proceeds from these transactions and cash on hand may not be sufficient to complete clinical development of any of our product candidates nor may it be sufficient to commercialize any product candidate. In addition, we completed a modified Dutch auction tender offer for our common shares in February 2020 and June 2023, which consumed $420 million and $14 thousand of our cash resources, respectively. We also distributed $75 million cash dividend to our investors in July 2021. Accordingly, we may require substantial additional capital to continue our clinical development and potential commercialization activities. Our future capital requirements depend on many factors, including but not limited to:

- the number of future product candidates we pursue;
- the scope, progress, results and costs of researching and developing any of our future product candidates, and conducting preclinical research and clinical trials;
- the timing of, and the costs involved in, obtaining regulatory approvals for any future product candidates we develop;
- the cost of future commercialization activities for our product candidates and the cost of commercializing any future products approved for sale;
- the cost of manufacturing our future products; and
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patents, including litigation costs and the outcome of any such litigation.

We are unable to accurately estimate the funds we will actually require to complete research and development of our product candidates or the funds required to commercialize any resulting product in the future or the funds that will be required to meet other expenses. Our operating plan may change as a result of many factors currently unknown to us, and our expenses may be higher than expected. Raising funds in the future may present additional challenges and future financing may not be available in sufficient amounts or on terms acceptable to us, if at all.

We currently have no source of product revenue and may never sustain profitability.

To date, we have not generated any revenue from commercial product sales. Our ability to generate revenue in the future from product sales and achieve profitability will depend upon our ability, alone or with any future collaborators, to commercialize products successfully, including any current product candidates or any product candidates that we may develop, in-license or acquire in the future. Even if we are able to achieve regulatory approval for any current or future product candidates, we do not know when any of these products will generate revenue from product sales, if at all. Our ability to generate revenue from product sales from any of our product candidates also depends on a number of additional factors, including our ability to:

- complete development activities, including the necessary clinical trials;
- complete and submit new drug applications, or NDAs, to the US Food and Drug Administration, or FDA, and obtain regulatory approval for indications for which there is a commercial market;
- complete and submit applications to, and obtain regulatory approval from, foreign regulatory authorities such as the European Medicines Agency, or EMA;
- establish our manufacturing operations;
- develop a commercial organization capable of sales, marketing and distribution for our product candidates and any products for which we obtain marketing approval and intend to sell ourselves in the markets in which we choose to commercialize on our own;
- find suitable distribution partners to help us market, sell and distribute our approved products in other markets;

- obtain coverage and adequate reimbursement from third-party payers, including government and private payers;
- achieve market acceptance for our products, if any;
- establish, maintain and protect our intellectual property rights; and
- attract, hire and retain qualified personnel.

In addition, because of the numerous risks and uncertainties associated with pharmaceutical product development, including that our product candidates may not advance through development or achieve the endpoints of applicable clinical trials, we are unable to predict the timing or amount of increased expenses, or if we will be able to sustain profitability. In addition, our expenses could increase beyond expectations if we decide to or are required by the FDA, or foreign regulatory authorities, to perform studies or trials in addition to those that we currently anticipate. Even if we are able to complete the development and regulatory process for our product candidates, we anticipate incurring significant costs associated with commercializing these products.

Even if we are able to generate revenues from the sale of any of our product candidates that may be approved, we may not become profitable and may need to obtain additional funding to continue operations. If we are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce our operations.

Our future success is dependent on the regulatory approval and commercialization of our product candidates.

We do not have any products that have gained regulatory approval. As a result, our ability to finance our operations and generate revenue, are substantially dependent on our ability to obtain regulatory approval for, and, if approved, to successfully commercialize our product candidates in a timely manner. We cannot commercialize our other product candidates in the U.S. without first obtaining regulatory approval for each product from the FDA; similarly, we cannot commercialize any product candidates outside of the U.S. without obtaining regulatory approval from comparable foreign regulatory authorities, including the EMA. The FDA review process typically takes years to complete and approval is never guaranteed. Before obtaining regulatory approvals for the commercial sale of any of our potential product candidates for a target indication, we must demonstrate with substantial evidence gathered in preclinical and well-controlled clinical studies, including two well-controlled Phase III studies, and, with respect to approval in the U.S. to the satisfaction of the FDA, and in Europe, to the satisfaction of the EMA, that the product candidate is safe and effective for use for that target indication; and that the manufacturing facilities, processes and controls are adequate. Obtaining regulatory approval for marketing of our current or future product candidates in one country does not ensure we will be able to obtain regulatory approval in other countries. A failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in other countries.

Even if any of our product candidates were to successfully obtain approval from the FDA or comparable foreign regulatory authorities, any approval might contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, or may be subject to burdensome post-approval studies or risk management requirements. If we are unable to obtain regulatory approval for our product candidates in one or more jurisdictions, or any approval contains significant limitations, we may not be able to obtain sufficient funding or generate sufficient revenue to continue the development of any of our other product candidates that we are developing or may discover, in-license, develop or acquire in the future. Also, any regulatory approval of our product candidates, once obtained, may be withdrawn. Furthermore, even if we obtain regulatory approval for any of our product candidates, their commercial success will depend on a number of factors, including the following:

- development of a commercial organization within XBiotech or establishment of a commercial collaboration with a commercial infrastructure;
- establishment of commercially viable pricing and obtaining approval for adequate reimbursement from third-party and government payers;

- our ability to manufacture quantities of our product candidates using commercially satisfactory processes and at a scale sufficient to meet anticipated demand and enable us to reduce our cost of manufacturing;
- our success in educating physicians and patients about the benefits, administration and use of our product candidates;
- the availability, perceived advantages, relative cost, relative safety and relative efficacy of alternative and competing treatments;
- the effectiveness of our own or our potential strategic collaborators' marketing, sales and distribution strategy and operations;
- acceptance as a safe and effective therapy by patients and the medical community; and
- a continued acceptable safety profile following approval.

Many of these factors are beyond our control. If we are unable to successfully commercialize our product candidates, we may not be able to earn sufficient revenues to continue our business.

New laws or regulations may be promulgated or modified in the United States, in Europe, or other jurisdictions that could impact our ability to receive the necessary approvals to successfully market and commercialize our product candidates.

The pharmaceutical and biotechnology industry is one of the most regulated on a state, federal and international level. There are a number of laws, regulations, and court decisions which impact the daily activities of our business. As a result, we must ensure that strategies and planning in relation to our product candidates are in line with the current regulations governing our industry. When there are changes in leadership, whether within the U.S., or elsewhere, we must anticipate the possibility of shifts in regulatory policies as they pertain to our business. New or modified regulations may impact our ability to quickly respond with updates to our programs. While we may be able to anticipate certain changes, policy statements often are not always translated into actionable legislation. We continue to track updates and changes internally to ensure we are in compliance with regulatory authority guidelines and expectations. Court decisions at both the state and federal level can also impact the way in which we operate and make specific product related program decisions. New laws, regulations, or court orders could materially alter or impact our ability to receive necessary approvals from regulatory authorities to market and commercialize our product candidates.

Because the results of earlier clinical trials are not necessarily predictive of future results, product candidates we advance into clinical trials, may not have favorable results in later clinical trials or receive regulatory approval.

Success in preclinical testing and early clinical trials does not ensure that later clinical trials will generate adequate data to demonstrate the efficacy and safety of an investigational drug. A number of companies in the pharmaceutical and biotechnology industries, including those with greater resources and experience, have suffered significant setbacks in clinical trials, even after seeing promising results in earlier clinical trials. We do not know whether the clinical trials we are conducting, or may conduct, will demonstrate adequate efficacy and safety to result in regulatory approval to market any of our product candidates in any particular jurisdiction. Even if we believe that we have adequate data to support an application for regulatory approval to market our product candidates, the FDA or other comparable foreign regulatory authorities may not agree and could require us to conduct additional research studies, including late-stage clinical trials. If late-stage clinical trials do not produce favorable results, our ability to achieve regulatory approval for any of our product candidates may be adversely impacted.

If we are unable to enroll subjects in clinical trials, we will be unable to complete these trials on a timely basis.

Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population, the proximity of subjects to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, ability to obtain and maintain patient consents, risk that enrolled subjects will drop out before completion, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating. Furthermore, we rely on clinical trial sites to ensure the proper and timely conduct of our clinical trials, and while we have agreements governing their committed activities, we have limited influence over their actual, day-to-day performance. We may experience delays in starting-up clinical trial sites in a timely manner, enrolling subjects in our trials, and may not be able to enroll a sufficient number of subjects to complete the trials.

If we experience delays in the completion or if there is termination of, any clinical trial of any current or future product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do, and jeopardize our ability to commence product sales, which would impair our ability to generate revenues and may harm our business, results of operations, financial condition and cash flows and future prospects. In addition, many of the factors that could cause a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business may fail.

The time required to obtain approval by the FDA and comparable foreign regulatory authorities is unpredictable, but typically takes several years following the commencement of preclinical studies and clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities and any shifts in regulatory policy. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate, and it is possible that none of the product candidates we are developing or may discover, in-license or acquire and seek to develop in the future will ever obtain regulatory approval.

Our product candidates could fail to receive marketing approval from the FDA or a comparable foreign regulatory authority for many reasons, including but not limited to:

- disagreement over the design or implementation of our clinical trials;
- failure to demonstrate that a product candidate is safe and effective;
- failure of clinical trials to meet the level of statistical significance required for approval;
- failure to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- disagreement over our interpretation of data from preclinical studies or clinical trials;
- disagreement over whether to accept efficacy results from clinical trial sites outside the United States where the standard of care is potentially different from that in the United States;

- the insufficiency of data collected from clinical trials of our product candidates to support the submission and filing of an NDA or other submission or to obtain regulatory approval;

- irreparable or critical compliance issues relating to our manufacturing and/clinical trial processes; or

- changes in the approval policies or regulations that render our preclinical and clinical data insufficient for approval.

The FDA or a comparable foreign regulatory authority may require more information, including additional preclinical or clinical data to support approval, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program altogether. Even if we do obtain regulatory approval, our product candidates may be approved for fewer or more limited indications than we request, approved contingent on the performance of costly post-marketing clinical trials, or approved with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. In addition, if any of our product candidates produce undesirable side effects or safety issues, the FDA may require the establishment of Risk Evaluation Mitigation Strategies, or REMS, or a comparable foreign regulatory authority may require the establishment of a similar strategy, that may, restrict distribution of our products and impose burdensome implementation requirements. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

Even if we believe any completed, current or planned clinical trials are successful, the FDA or a comparable foreign regulatory authority may not agree that our completed clinical trials provide adequate data on the safety or efficacy of our product candidates, permitting us to proceed to additional clinical trials. Approval by comparable foreign regulatory authorities does not ensure approval by the FDA and approval by one or more foreign regulatory authorities does not ensure approval by regulatory authorities in other countries or by the FDA. However, a failure or delay in obtaining regulatory approval in one country may have a negative impact on the regulatory process in others. We may not be able to file for regulatory approvals, and even if we file, we may not receive the necessary approvals to commercialize our products in any market.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following any marketing approval.

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authority. If toxicities occur in our current or future clinical trials they could cause delay or even the discontinuation of further development of our product candidates, which would impair our ability to generate revenues and would have a material adverse effect our business, results of operations, financial condition and cash flows and future prospects. There can be no assurance that side effects from our product candidates in future clinical trials or that side effects in general will not prompt the discontinued development or possible market approval of our product candidates. If serious side effects or other safety or toxicity issues are experienced in our clinical trials in the future, we may not receive approval to market any of our product candidates, which could prevent us from ever generating revenues from commercial product sales or sustaining profitability. Results of our trials could reveal an unacceptably high severity and prevalence of side effects. In such an event, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. Any of these occurrences may have a material adverse effect on our business, results of operations, financial condition and cash flows and future prospects.

Additionally, if any of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such product, a number of potentially significant negative consequences could result, including:

- we may be forced to suspend marketing of such product;
- regulatory authorities may withdraw their approvals of such product;
- regulatory authorities may require additional warnings on the label that could diminish the usage or otherwise limit the commercial success of such product;
- the FDA or other regulatory bodies may issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings about such product;
- the FDA may require the establishment or modification of REMS or a comparable foreign regulatory authority may require the establishment or modification of a similar strategy that may, for instance, restrict distribution of our product and impose burdensome implementation requirements on us;
- we may be required to change the way the product is administered or conduct additional clinical trials;
- we could be sued and held liable for harm caused to subjects or patients;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved.

Even if our product candidates receive regulatory approval, they may still face future challenges, including ongoing regulatory oversight and marketing challenges.

Even if we obtain regulatory approval for any of our product candidates, it would be subject to ongoing requirements by the FDA and comparable foreign regulatory authorities governing the manufacture, quality control, further development, labeling, packaging, storage, distribution, safety surveillance, import, export, advertising, promotion, recordkeeping and reporting of safety and other post-market information. The safety profile of any product will continue to be closely monitored by the FDA and comparable foreign regulatory authorities after approval. If the FDA or comparable foreign regulatory authorities become aware of new safety information after approval of any product candidate, they may require labeling changes or establishment of a REMS or similar strategy, impose significant restrictions on a product's indicated uses or marketing, or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance. For example, the label ultimately approved for any product candidate, if it achieves marketing approval, may include restrictions on use.

In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current good manufacturing practices, or cGMP, and other regulations. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, our manufacturing facility, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. If we, our product candidates or our manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters or untitled letters;

- impose restrictions on the marketing or manufacturing of the product candidates;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;
- require us or any future collaborator to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to applications filed by us;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products, refuse to permit the import or export of products, or require us to initiate a product recall.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue.

The FDA strictly regulates the advertising and promotion of drug products, and drug products may only be marketed or promoted for their FDA approved uses, consistent with the product's approved labeling. Advertising and promotion of any product candidate that obtains approval in the U.S., and is covered by federal insurance programs such as Medicare or Medicaid, will be heavily scrutinized by the FDA, the Department of Justice, (DOJ), the Office of Inspector General of the Department of Health and Human Services, (HHS), state attorneys general, members of Congress and the public. Violations, including promotion of our products for unapproved or off-label uses, are subject to enforcement letters, inquiries and investigations, and civil, criminal and/or administrative sanctions by the FDA and/or the DOJ. Additionally, advertising and promotion of, any product candidate that obtains approval outside of the U.S. will be heavily scrutinized by comparable foreign regulatory authorities.

In the U.S., engaging in impermissible promotion of our future products for off-label uses can also subject us to false claims litigation under federal and state statutes, which can lead to civil, criminal and/or administrative penalties and fines and corporate integrity agreements that materially restrict the manner in which we promote or distribute our drug products. The federal False Claims Act, allows any individual to bring a lawsuit against a pharmaceutical company on behalf of the federal government alleging submission of false or fraudulent claims, or causing to present such false or fraudulent claims, for payment by a federal program, such as Medicare or Medicaid. If the government prevails in the lawsuit, the individual may share in any fines or settlement funds. Since 2004, False Claims Act lawsuits against pharmaceutical companies have increased significantly in volume and breadth, leading to several substantial civil and criminal settlements based on certain sales practices promoting off-label drug uses. This growth in litigation has increased the risk that a pharmaceutical company will have to defend a false claims action, pay settlement fines or restitution, agree to comply with burdensome reporting and compliance obligations, and be excluded from Medicare, Medicaid and other federal and state healthcare programs. If we do not lawfully promote our approved products, we may become subject to such litigation and, if we are not successful in defending against such actions, those actions could have a material adverse effect on our business, results of operations, financial condition and cash flows and future prospects.

Existing government regulations may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and/or be subject to fines or enhanced government oversight and reporting obligations, which would adversely affect our business, prospects and ability to sustain profitability.

Failure to obtain regulatory approval in foreign jurisdictions would prevent our product candidates from being marketed in those jurisdictions.

In order to market and sell our products in the European Union and many other jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the U.S. generally includes all of the risks associated with obtaining FDA approval. Additionally, in many countries outside the U.S., it is required that the product be approved for reimbursement before the product can be effectively commercialized in that country. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. We may not obtain approvals from regulatory authorities outside the U.S. on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the U.S. does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. A failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in others. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any market. If we are unable to obtain approval of any of our product candidates by regulatory authorities in the European Union or another jurisdiction, the commercial prospects of that product candidate may be significantly diminished and our business prospects could decline.

Even if we are able to commercialize our product candidates, the products may not receive coverage and adequate reimbursement from third-party payers, which could harm our business.

Our ability to commercialize any products successfully will depend, in part, on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government authorities, private health insurers, health maintenance organizations and third-party payers. Patients who are prescribed medications for the treatment of their conditions generally rely on third-party payers to reimburse all or part of the costs associated with their prescription drugs. Coverage and adequate reimbursement from government healthcare programs, such as Medicare and Medicaid, and private health insurers are critical to new product acceptance. Patients are unlikely to use our product candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our product candidates. A primary trend in the US healthcare industry and elsewhere is cost containment. As a result, government authorities and other third-party payers have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payers are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Third-party payers may also seek additional clinical evidence, beyond the data required to obtain marketing approval, demonstrating clinical benefits and value in specific patient populations before covering our products for those patients. We cannot be sure that coverage and adequate reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement are not available or are available only at limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, obtaining coverage does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sales and distribution. Interim reimbursement levels for new drugs, if applicable, may also be insufficient to cover our costs, and may only be temporary. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used. Reimbursement rates may also be based in part on existing reimbursement amounts for lower cost drugs or may be bundled into the payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payers and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the U.S. Coverage and reimbursement for drug products can differ significantly from payer to payer. As a result, the coverage and reimbursement determination process is often a time-consuming and costly process with no assurance that coverage and adequate reimbursement will be obtained or applied consistently. Third-party payers often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. Our inability to promptly obtain coverage and profitable reimbursement rates from both government-funded and private payers for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products, and our overall financial condition.

We have never marketed a drug before, and if we are unable to establish an effective sales force and marketing infrastructure, or enter into acceptable third-party sales and marketing or licensing arrangements, we may be unable to generate any revenue.

We do not currently have a comprehensive infrastructure for the sales, marketing and distribution of pharmaceutical drug products. The cost of establishing and maintaining such an infrastructure may exceed the cost-effectiveness of doing so. In order to market any products that may be approved by the FDA and comparable foreign regulatory authorities, we must build our sales, marketing, managerial and other non-technical capabilities or make arrangements with third parties to perform these services for which we would incur substantial costs. If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate product revenue and may not sustain profitability. We will be competing with many companies that have extensive and well-funded sales and marketing operations. Without an internal commercial organization or the support of a third party to perform sales and marketing functions, or a combination of both, we may be unable to compete successfully against more established companies.

Our product candidates, if approved, may not achieve adequate market acceptance among physicians, patients, and healthcare payers and others in the medical community necessary for commercial success.

Even if we obtain regulatory approval for any of our product candidates, such product(s) may not gain market acceptance among physicians, healthcare payers, patients or the medical community within the U.S. or globally. Our commercial success also depends on coverage and adequate reimbursement of our product candidates by third-party payers, including government payers, generally, which may be difficult or time-consuming to obtain, may be limited in scope and may not be obtained in all jurisdictions in which we may seek to market our products. Market acceptance of any of our product candidates for which we receive approval depends on a number of factors, including:

- the efficacy and safety of such product candidates as demonstrated in clinical trials;
- the clinical indications for which the product candidate is approved;
- acceptance by physicians and patients of the product candidate as a safe and effective treatment;
- the potential and perceived advantages of product candidates over alternative treatments;
- the safety of product candidates seen in a broader patient group, including a product candidate’s use outside the approved indications;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA or other regulatory authorities;

- the timing of market introduction of our products as well as competitive products;
- the cost of treatment in relation to alternative treatments;
- the availability of coverage and adequate reimbursement and pricing by third-party payers and government authorities;
- relative convenience and ease of administration;
- the effectiveness of our sales and marketing efforts and those of our collaborators; and
- unfavorable publicity relating to the product candidate or the Company.

If any of our product candidates are approved but fail to achieve market acceptance among physicians, patients, or healthcare payers, we will not be able to generate significant revenues, which would compromise our ability to sustain profitability.

Our research programs may not succeed.

XBiotech has positioned itself with a pipeline of potential drug candidates at various stages of development. Even though we have multiple drugs in development at this time, none of these research programs may succeed. There are several reasons why a drug program may fail, including the following:

- In the development stage, we may be unable to develop a therapy, which would mean us succeeding in isolating appropriate antibodies to reach the clinical trial stage;
- Any partnerships for the development of antibodies could fail to produce results that would necessitate clinical trials;
- We may not receive approval from regulatory bodies to move from early stage clinical trials to later stage clinical trials;
- Even if we are able to move to later stage clinical trials, it may prove to be difficult to enroll patients into the studies according to schedule, or at all;
- During the clinical trial, there could be unexpected serious adverse events causing severe injury or death in patients, requiring us to cease further enrollment or causing regulatory authorities to place the trial on clinical hold for an indefinite period of time;
- If a clinical trial is completed, we may not have the appropriate personnel to submit a marketing application to regulatory authorities for approval, and to further respond to the variety of follow up questions that regulatory authorities may have during the review process;
- Regulatory authorities may reject drug candidates for a variety of reasons, preventing us from proceeding with marketing and commercialization of approved products; and
- We may run out of the funds necessary to complete development for any of our potential drug candidates.

Even an effective drug candidate might not be commercially successful.

Even if we ultimately succeed in creating a safe and effective drug, as determined by regulatory authorities, based on our current product pipeline, there is no assurance it would be commercially successful. Competitive products might become available faster or with lower costs or adverse risks to patients, resulting in few sales of any product developed by XBiotech. Occurrences of certain disease indications, such as those in our pipeline, might become sufficiently rare, or victims might be sufficiently impoverished, that commercial production is uneconomic. Furthermore, we must have sufficient buy-in from patients and healthcare professionals to guarantee market exposure for our drug candidates. If the end-users are not reached with our products, then it will be difficult to generate revenue from our development efforts. And even though we could obtain regulatory approval for any of our drug candidates, it is not necessarily the case that government or third-party payers will decide to add our products to their respective prescription drug formularies for reimbursement, thus inhibiting the ability for our drug candidates to reach the target patient populations, and health care professionals serving those patients.

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

The development and commercialization of new drug products is highly competitive. We face competition with respect to our current or future product candidates to treat any relevant indication(s). There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of the disease indications for which we are developing our future product candidates. Some of these competitive products and therapies are based on scientific approaches that are the same as or similar to our approach, and others are based on entirely different approaches. Potential competitors include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

More established companies may have a competitive advantage over us due to their greater size, cash flows and institutional experience. Compared to us, many of our competitors may have significantly greater financial, technical and human resources. As a result of these factors, our competitors may obtain regulatory approval of their products before we do, which will limit our ability to develop or commercialize any of our product candidates. In addition, many companies are developing new therapeutics to supplant or expand upon the standard of care for a number of diseases, as a result, we cannot predict what the standard of care will be as our product candidates progress through clinical development.

Our failure to successfully identify, acquire, develop and commercialize additional product candidates or approved products could impair our ability to grow.

Although a substantial amount of our efforts will focus on the continued clinical testing and potential approval of our current product candidates, a key element of our growth strategy is to acquire, develop and/or market additional products and product candidates. All of these potential product candidates remain in the discovery and clinical study stages. Research programs to identify product candidates require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. Because our internal research capabilities are limited, we may be dependent upon pharmaceutical and biotechnology companies, academic scientists and other researchers to sell or license products or technology to us. The success of this strategy depends partly upon our ability to identify, select and acquire promising pharmaceutical product candidates and products. The process of proposing, negotiating and implementing a license or acquisition of a product candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing and sales resources, may compete with us for the license or acquisition of product candidates and approved products. We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. Any product candidate that we acquire may require additional development efforts prior to commercial sale, including extensive clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to risks of failure typical of pharmaceutical product development, including the possibility that a product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot provide assurance that any products that we develop or approved products that we acquire will be manufactured profitably or achieve market acceptance.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the testing of our product candidates in clinical trials and will face an even greater risk if we commercially sell any products that we may develop. Product liability claims may be brought against us by subjects enrolled in our clinical trials, patients, healthcare providers or others using, administering or selling our products. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- termination of clinical trial sites or entire clinical trial programs;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to clinical trial subjects or patients;
- loss of revenue;
- diversion of management and scientific resources from our business operations; and
- the inability to commercialize our product candidates.

We will obtain insurance coverage for products to include the sale of commercial products if we obtain marketing approval for our product candidates, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us, particularly if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

We will need to expand our operations and grow the size of our organization in the future, and we may experience difficulties in managing this growth.

As of December 31, 2023, we had 82 employees. As our development and commercialization plans and strategies develop, or as a result of any future acquisitions, we will need additional managerial, operational, sales, marketing, scientific, and financial headcount and other resources. Our management, personnel and systems currently in place may not be adequate to support this future growth. Future growth would impose significant added responsibilities on members of management, including:

- managing our clinical trials effectively, which we anticipate potentially being conducted at numerous clinical sites on a global scale;
- identifying, recruiting, maintaining, motivating and integrating additional employees with the expertise and experience we will require;
- managing our internal development efforts effectively while complying with our contractual obligations to licensors, licensees, contractors and other third parties;

- managing additional relationships with various strategic partners, suppliers and other third parties;
- improving our managerial, development, operational and finance reporting systems and procedures; and
- expanding our facilities.

Our failure to accomplish any of these tasks could prevent us from successfully growing our Company.

We may never achieve any of the potential milestone payments that were negotiated as a part of the Janssen Transaction.

As part of the Janssen Transaction, we are eligible to receive milestone payments of $150 million for each instance that Janssen, in its sole and absolute discretion, develops pharmaceutical products that contain Bermekimab and that are for non-dermatological indications, provided that Janssen receives certain required commercial authorizations for such products within a specified timeframe. We are entitled to earn up to four milestone payments, for a maximum of $600 million. However, because the payment of these funds is subject to Janssen's business decisions and discretion, as well as regulatory approvals and other factors outside our control, we may never receive any of these amounts. If we do not receive all or any of the milestone payments, we may be required to seek additional funding from other sources, which may not be available on terms acceptable to us or at all.

We are highly dependent on our Chief Executive Officer.

Our future success depends in significant part on the continued service of our Chief Executive Officer, John Simard. Mr. Simard is critical to the strategic direction and overall management of our company as well as our research and development process. Although we have an employment agreement with Mr. Simard, it has no specific duration. The loss of Mr. Simard could adversely affect our business, financial condition and operating results.

We depend on key personnel to operate our business. If we are unable to retain, attract and integrate qualified personnel, our ability to develop and successfully grow our business could be harmed.

In addition to the continued services of Mr. Simard, we believe that our future success is highly dependent on the contributions of our significant employees, as well as our ability to attract and retain highly skilled and experienced sales, research and development and other personnel in the United States and abroad. Some of our significant employees include our Chief Scientific Officer, our Vice President of Quality Assurance, our Vice President of Quality Control, our Principal Financial Officer and Principal Accounting Officer. Changes in our management team may be disruptive to our business.

All of our employees, including our Chief Executive Officer, are free to terminate their employment relationship with us at any time, subject to any applicable notice requirements, and their knowledge of our business and industry may be difficult to replace. If one or more of our executive officers or significant employees leaves, we may not be able to fully integrate new personnel or replicate the prior working relationships, and our operations could suffer. Qualified individuals with the breadth of skills and experience in the pharmaceutical industry that we require are in high demand, and we may incur significant costs to attract them. Many of the other pharmaceutical companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Our failure to attract and retain key personnel could impede the achievement of our research, development and commercialization objectives.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations in the U.S. and elsewhere, including, as a result of our leased laboratory space, those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes.

We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain insurance for employee injury to cover us for costs and expenses, we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological or hazardous materials. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations may also result in substantial fines, penalties or other sanctions.

Business disruptions caused by natural disasters, infrastructure interruptions or other public health threats could seriously harm our future revenues and financial condition and increase our costs and expenses.

Our operations could be subject to earthquakes, power shortages or outages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics such as contagious disease outbreaks, and other natural or manmade disasters or business interruptions, for which we are predominantly self-insured. We do not carry insurance for all categories of risk that our business may encounter. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third-parties to supply various items which are critical for producing our product candidates. Our ability to produce clinical supplies of product candidates could be disrupted, if the operations of these suppliers are affected by a man-made or natural disaster, a public health crisis or other business interruption. For example, the ongoing coronavirus threat has spread to a number of countries, including the United States and various countries in Europe, resulting in the declaration by the World Health Organization of a global pandemic and the announcement of extended travel restrictions, business shutdowns, cancellations and prohibitions of large public gatherings and declarations of states of emergency in cities, states and countries around the world. The imposition of any of these restrictions in one of the regions where our facilities or those of our third-party suppliers are located would have a disproportionately negative impact on us. The extent of the ultimate impact to us, our significant suppliers and our general infrastructure resulting from concentration in certain geographical areas is unknown and cannot be estimated, but our operations and financial condition would likely suffer in the event of a major earthquake, fire or other natural disaster or public health threat such as the coronavirus pandemic in one or more of those areas. Further, any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our business, results of operations, financial condition and cash flows from future prospects.

Risks Related to Intellectual Property

If *we are unable to obtain or protect intellectual property rights, our competitive position could be harmed.*

We depend on our ability to protect our proprietary technology. We rely on trade secret, patent, copyright and trademark laws, and confidentiality, licensing and other agreements with employees and third parties, all of which offer only limited protection. Our commercial success will depend in large part on our ability to obtain and maintain patent protection in the U.S. and other countries with respect to our proprietary technology and products. Where we deem appropriate, we seek to protect our proprietary position by filing patent applications in the U.S. and abroad related to our novel technologies and products that are important to our business. The patent positions of biotechnology and pharmaceutical companies generally are highly uncertain, involve complex legal and factual questions and have in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patents, including those patent rights licensed to us by third parties, are highly uncertain.

The steps we have taken to protect our proprietary rights may not be adequate to preclude misappropriation of our proprietary information or infringement of our intellectual property rights, both inside and outside the U.S. The rights already granted under any of our currently issued patents and those that may be granted under future issued patents may not provide us with the proprietary protection or competitive advantages we are seeking. If we are unable to obtain and maintain patent protection for our technology and products, or if the scope of the patent protection obtained is not sufficient, our competitors could develop and commercialize technology and products similar or superior to ours, and our ability to successfully commercialize our technology and products may be adversely affected.

With respect to patent rights, we do not know whether our pending patent applications for any of our technologies or product candidates will result in the issuance of patents that protect such technologies or product candidates, or if any of our issued patents will effectively prevent others from commercializing competitive technologies and products. Our pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Further, the examination process may require us to narrow the claims for our pending patent applications, which may limit the scope of patent protection that may be obtained if these applications are granted. Because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, issued patents that we own or have licensed from third parties may be challenged in the courts or patent offices in the U.S. and abroad. Such challenges may result in the loss of patent protection, the narrowing of claims in such patents or the invalidity or unenforceability of such patents, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection for our technology and products. Protecting against the unauthorized use of our patented technology, trademarks and other intellectual property rights is expensive, difficult and, in some cases, not be possible. In some cases, it may be difficult or impossible to detect third-party infringement or misappropriation of our intellectual property rights, even in relation to issued patent claims, and proving any such infringement may be even more difficult.

Intellectual property rights do not necessarily address all potential threats to any competitive advantage we may have.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- Others may be able to make compounds that are the same as or similar to our current or future product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed.
- We might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed.
- We or any of our licensors or strategic partners might not have been the first to file patent applications covering certain of our inventions.
- Others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights.
- It is possible that our pending patent applications will not lead to issued patents.
- Issued patents that we own or have exclusively licensed may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors.

- Our competitors might conduct research and development activities in the U.S. and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets.

- We may not develop additional proprietary technologies that are patentable.

- The patents of others may have an adverse effect on our business.

Our technology may be found to infringe upon third-party intellectual property rights.

Third parties, may in the future, assert claims or initiate litigation related to their patent, copyright, trademark and other intellectual property rights in technology that is important to us. The asserted claims and/or litigation could include claims against us, our licensors or our suppliers alleging infringement of intellectual property rights with respect to our products or components of those products. Regardless of the merit of the claims, they could be time consuming, result in costly litigation and diversion of technical and management personnel, or require us to develop a non-infringing technology or enter into license agreements. We cannot assure you that licenses will be available on acceptable terms, if at all. Furthermore, because of the potential for significant damage awards, which are not necessarily predictable, it is not unusual to find even arguably unmeritorious claims resulting in large settlements. If any infringement or other intellectual property claim made against us by any third party is successful, or if we fail to develop non-infringing technology or license the proprietary rights on commercially reasonable terms and conditions, our business, operating results and financial condition could be materially and adversely affected.

If our products, methods, processes and other technologies infringe upon the proprietary rights of other parties, we could incur substantial costs and we may have to:

- obtain licenses, which may not be available on commercially reasonable terms, if at all;

- abandon an infringing drug or therapy candidate;

- redesign our products or processes to avoid infringement;

- stop using the subject matter claimed in the patents held by others;

- pay damages; or

- defend litigation or administrative proceedings which may be costly whether we win or lose, and which could result in a substantial diversion of our financial and management resources.

We may need to license intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.

A third party may hold intellectual property, including patent rights that are important or necessary to the development of our products. It may be necessary for us to use the patented or proprietary technology of a third party to manufacture, or otherwise commercialize, our own technology or products, in which case we would be required to obtain a license from such third party. Licensing such intellectual property may not be available or may not be available on commercially reasonable terms, which could have a material adverse effect on our business and financial condition.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patents for some of our technology and product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside of the U.S. are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

Risks Related to Owning Shares of Our Common Stock

Our share price may be volatile, which could subject us to securities class action lawsuits and prevent you from being able to sell your shares at or above the price at which you purchased them.

Our stock could be subject to wide fluctuations in response to many risk factors listed in this section, and others beyond our control, including:

- results of our clinical trials;
- results of clinical trials of our competitors' products;
- regulatory actions with respect to our products or our competitors' products;
- actual or anticipated fluctuations in our financial condition and operating results;
- actual or anticipated changes in our growth rate relative to our competitors;
- actual or anticipated fluctuations in our competitors' operating results or changes in their growth rate;
- competition from existing products or new products that may emerge;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- issuance of new or updated research or reports by securities analysts;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- delisting of the Company's common shares from the exchange on which they trade due to the Company not being in compliance with the listing requirements of the exchange;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- additions or departures of key management or scientific personnel;

- disputes or other developments related to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders or our other shareholders;
- market conditions for biopharmaceutical stocks in general; and
- general economic and market conditions.

Furthermore, the stock markets have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many companies. These fluctuations often have been unrelated or disproportionate to the operating performance of those companies. In particular, stock markets have experienced extreme volatility in the first quarter of 2020 due to the ongoing coronavirus pandemic and investor concerns and uncertainty related to the impact of the outbreak on the economies of countries worldwide. These broad market and industry fluctuations, as well as general economic, political and market conditions such as recessions, interest rate changes or international currency fluctuations, may negatively impact the market price of shares of our common stock. In addition, such fluctuations could subject us to securities class action litigation, which could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business. If the market price of shares of our common stock does not exceed your buying price, you may not realize any return on your investment in us and may lose some or all of your investment.

Our directors, executive officers and principal shareholders continue to have substantial control over our company and could delay or prevent a change in corporate control.

As of March 15, 2024 our directors, executive officers and principal shareholders, together with their affiliates, beneficially own, in the aggregate, at least 11.8 million shares or approximately 38.7% of our outstanding common stock, and could own approximately 14.3 million shares or approximately 43.5% of our outstanding common stock if they fully exercise their outstanding stock options. As a result, these shareholders, if acting together, have the ability to determine the outcome of matters submitted to our shareholders for approval, including the election of directors and any merger, consolidation or sale of all or substantially all of our assets. In addition, these persons, acting together, have the ability to control the management and affairs of the Company. Accordingly, this concentration of ownership may harm the market price of our common stock by:

- delaying, deferring or preventing a change in control of the Company;
- impeding a merger, consolidation, takeover or other business combination involving the Company; or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of the Company.

We have broad discretion in the use of the net proceeds from the Janssen Transaction and may not use them effectively.

We intend to continue to allocate the net proceeds that we received from our public offerings and the Janssen Transaction to fund discovery and development of our next generation True Human™ anti-IL-1α antibody program and to advance other antibody therapeutics in our pipeline. However, our management will have broad discretion in the actual application of the net proceeds, and we may elect to allocate proceeds differently if we believe it would be in our best interests to do so. For example, in February 2020, we completed a cash tender offer in which we repurchased $420 million of our common shares. In July 2021, we distributed $75 million cash dividend to our shareholders. Our shareholders may not agree with the manner in which our management chooses to allocate and spend the net proceeds. Our management may also fail to apply these funds effectively, which could have a material adverse effect on our business. We may invest our cash on hand in a manner that does not produce income or that loses value.

Provisions in our charter documents under Canadian law could make an acquisition of us, which may be beneficial to our shareholders, more difficult.

Our authorized preferred capital stock is available for issuance from time to time at the discretion of our Board of Directors, without shareholder approval. Our Articles of Incorporation ("Articles") grant our Board of Directors the authority, subject to the corporate law of British Columbia, to determine or alter the special rights and restrictions granted to or imposed on any wholly unissued series of preferred shares, and such rights may be superior to those of our common stock.

Limitations on the ability to acquire and hold our common stock may be imposed by the Competition Act (Canada). This legislation permits the Commissioner of Competition of Canada to review any acquisition of a significant interest in us. This legislation grants the Commissioner jurisdiction to challenge such an acquisition before the Canadian Competition Tribunal if the Commissioner believes that it would, or would be likely to, result in a substantial lessening or prevention of competition in any market in Canada. The Investment Canada Act (Canada) subjects an acquisition of control of a company by a non-Canadian to government review if the value of our assets as calculated pursuant to the legislation exceeds a threshold amount. A reviewable acquisition may not proceed unless the relevant minister is satisfied that the investment is likely to be a net benefit to Canada.

Any of the foregoing could prevent or delay a change of control and may deprive or limit strategic opportunities for our shareholders to sell their shares and/or affect the market price of our shares.

We may be a passive foreign investment company for US tax purposes which may negatively affect US investors.

We do not believe XBiotech is an "Investment Company"; instead, we believe it is a bona fide biopharmaceutical entity engaged in active pharmaceutical R&D, evidenced by the recent sale of its drug candidate Bermekimab for $750 million and up to $600 million in potential milestone payments and our extensive ongoing R&D activity. However, arbitrary definitions used to define a passive foreign investment company (PFIC) for US tax purposes have made some financial analysts suggest we are a PFIC. Particularly, based on the blind criteria that if 75% or more of gross income is passive income, with nothing else considered, then a company may be held to be a PFIC. Some years we don't have income, since we only will have income when for example we sell one of our drugs or when we get a drug to market and generate sales. But we do keep the company's cash in an interest bearing bank account or interest earning instruments. This generates interest income (or passive income) on our funds. We believe that to suggest that such bank account interest makes us a PFIC is absurd; this would suggest that we cannot keep our cash in a bank account and that interest on the Company's funds supersedes any other consideration in defining the the actual operations and essential nature of the Company. XBiotech will never accept an arbitrary and erroneous definition that could potentially penalize the Company and its shareholders and will oppose any effort to do so by the tax authorities. There is a risk that that tax authorities could successfully assert our PFIC status, and in such event shares held by a US person in that year will be PFIC shares for that year and all for subsequent years in which they are held by that person. PFIC rules can apply differently to different US shareholders depending on whether a specific shareholder has made certain elections with respect to the ownership of PFIC shares. Because these rules are complex and apply differently based upon whether and when a US shareholder has made certain elections, new and existing US shareholders should consult with their tax advisors as to the potential tax implications of acquiring, owning and disposing of our stock.

We are governed by the corporate laws in British Columbia, Canada which in some cases have a different effect on shareholders than the corporate laws in Delaware, United States.

The material differences between the BCBCA as compared to the Delaware General Corporation Law (DGCL) which may be of most interest to shareholders include the following:

(i) for material corporate transactions (i.e. mergers and amalgamations, other extraordinary corporate transactions, amendments to our Articles) the BCBCA generally requires two-thirds majority vote by shareholders, whereas DGCL generally only requires a majority vote of shareholders;

(ii) the quorum for shareholders meetings is not prescribed under the BCBCA and is only two persons representing 20% of the issued shares under our Articles, whereas under DGCL, quorum requires a minimum of one-third of the shares entitled to vote to be present and companies' certificates of incorporation frequently require a higher percentage to be present;

(iii) under the BCBCA, a holder of 5% or more of our common stock can requisition a special meeting at which any matters that can be voted on at our annual meeting can be considered, whereas the DGCL does not give this right;

(iv) our Articles require two-thirds majority vote by shareholders to pass a resolution for one or more directors to be removed, whereas DGCL only requires the affirmative vote of a majority of the shareholders; however, many public company charters limit removal of directors to a removal for cause; and

(v) our Articles may be amended by resolution of our directors to alter our authorized share structure, including to consolidate or subdivide any of our shares, whereas under DGCL, a majority vote by shareholders is generally required to amend a corporation's certificate of incorporation and a separate class vote may be required to authorize alterations to a corporation's authorized share structure.

We cannot predict if investors will find our common stock less attractive because of these material differences. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our share price may be more volatile.

General Risk Factors

Raising additional capital may cause dilution to our existing shareholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

The terms of any financing arrangements we enter into may adversely affect the holdings or the rights of our shareholders and the issuance of additional securities, by us, or the possibility of such issuance, may cause the market price of our shares to decline. The sale of additional equity or convertible securities would dilute all of our shareholders. The incurrence of indebtedness would result in increased fixed payment obligations and, potentially, the imposition of restrictive covenants. Those covenants may include limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaborators or otherwise at an earlier stage than otherwise would be desirable resulting in the loss of rights to some of our product candidates or other unfavorable terms, any of which may have a material adverse effect on our business, operating results and prospects. Additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our products.

Future sales, or the possibility of future sales, of a substantial number of our common stock could adversely affect the price of the shares and dilute shareholders.

We may have a limited ability to use some or all of our net operating loss and research tax credit carryforwards in the future.

As a result of prior operating losses and research and development activities, we have net operating loss, or "NOL," and research tax credit carryforwards (collectively, the "carryforwards") for U.S. federal income tax purposes. Under Section 382 of the Internal Revenue Code of 1986, as amended, substantial changes in the Company's ownership may limit the amount of carryforwards that could be utilized annually in the future to offset U.S. taxable income and/or income tax. Specifically, this limitation may arise in the event of a cumulative change in ownership of the Company of more than 50% within a three-year period. Any such annual limitation may significantly reduce the utilization of the carryforwards before they expire.

Future sales of a substantial number of our common stock, or the perception that such sales will occur, could cause a decline in the market price of our common stock. As of March 15, 2024, we had 30,450,881 common shares outstanding.

In the future, we may issue additional common stock or other equity or debt securities convertible into common stock in connection with a financing, acquisition, litigation settlement, employee arrangements or otherwise. Any such issuance could result in substantial dilution to our existing shareholders and could cause our common share price to decline.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, shareholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

We are required to disclose changes made in our internal controls and procedures on a quarterly basis and our management is required to assess the effectiveness of these controls annually. However, for as long as we are a "smaller reporting company" with under $100 million in annual revenue, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404. An independent assessment of the effectiveness of our internal controls could detect problems that our management's assessment might not.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

The Company owns 48 acres of industrial-zoned property located five miles from Austin's central business district at the address of 5217 Winnebago Ln, Austin, TX, 78744. In 2016 the company built a new combined R&D and manufacturing facility on this property. The Company uses this facility to conduct research, discover new product candidates, produce products for clinical studies and provide administrative space to support its drug development and other activities. In 2019, XBiotech constructed a new facility to house infectious disease and animal facilities. Located in a separate building on our campus, just a short walk from the Company's main manufacturing headquarters, the new facility incorporates an animal biological safety level 2 (ABSL2) laboratory and other laboratories for developing and testing Company's True Human™ antibodies against infectious disease targets. XBiotech owns the 48-acre campus—and all structures on the property—debt-free and envisions further expansion of facilities on the property. In 2024 the Company is planning to construct a new, multi-story 46,000ft2 R&D facility adjacent to the existing R&D facility on the Campus. The Company is also planning to construct a 5,000 ft2 research laboratory as part of a network of structures.

ITEM 3. LEGAL PROCEEDINGS

The Company is not currently subject to any material legal proceedings.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock began trading on the NASDAQ Global Select Market on April 15, 2015 under the symbol "XBIT." Prior to that time, there was no established public trading market for our common stock.

Holders of record

There were 11 record holders of our common stock as of February 26, 2024.

Dividends

In July 2021, we paid $2.50 per share in dividends to shareholders. We currently intend to retain any earnings for future growth and, therefore, do not expect comparable cash dividends will continue to be paid in the foreseeable future. Any future determination to declare cash dividends will be made at the discretion of our Board of Directors, subject to applicable laws, and will depend on a number of factors, including our financial condition, results of operations, capital requirements, contractual restrictions, general business conditions, and other factors that our Board of Directors may deem relevant.

Unregistered Sales of Equity Securities

[None.]

Issuer Purchases of Equity Securities

[None.]

ITEM 6. RESERVED

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with our audited consolidated financial statements for the year ended December 31, 2023 and related notes thereto, which have been prepared in accordance with U.S. GAAP, included elsewhere in this annual report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this annual report on Form 10-K, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and is subject to the safe harbor created by those sections. As a result of many factors, including those factors set forth in the "Risk Factors" section of this annual report on Form 10-K, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. For more information, see "Cautionary Statement About Forward-Looking Statements." In particular, we encourage you to review the risks and uncertainties described in "Risk Factors" in this annual report on Form 10-K. These forward-looking statements are made as of the date of this report, and we do not intend, and do not assume any obligation, to update these forward-looking statements, except as required by law. All dollar amounts stated herein are in U.S. dollars unless specified otherwise.

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 accumulated deficit earnings as of December 31, 2023 was ($52.3) million. We had a net loss of $24.6 million for the year ended December 31, 2023, compared to a net loss of $32.9 million for the year ended December 31, 2022. During the fiscal year of 2024, we don't expect to generate any revenues. 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 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, 2023, we had 82 employees.

Components of Results of Operations

Revenues

Prior to receiving payments under the clinical manufacturing agreement entered in connection with the Janssen Transaction, we had not generated any revenue. Under the clinical manufacturing agreement, we manufactured 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 continued to manufacture Bermekimab through November 2022. The contract terminated in November 2022. 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.

Operating Expenses

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, share-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 December 31, 2023, we have recorded total research and development expenses, including share-based compensation, of $311.9 million. Our total research and development expenses for the year ended December 31, 2023 was $32.8 million, compared to $31.5 million the year ended December 31, 2022. Share-based compensation accounted for $2.8 million for the year ended December 31, 2023 and $3.6 million for the year ended December 31, 2022.

Research and development expenses as a percentage of total operating expenses was 88% for the year ended December 31, 2023, and 83% for the year ended December 31, 2022. The percentages, excluding share-based compensation, were 88% for the year ended December 31, 2023, and 85% for the year ended December 31, 2022.

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, share–based compensation, and professional fees for legal services. Our total general and administration expenses was $4.7 million for the year ended December 31, 2023, and $6.3 million for the year ended December 31, 2022. Share-based compensation accounted for $0.5 million for the year ended December 31, 2023, and $1.4 million for the year ended December 31, 2022.

General and administrative expenses as a percentage of total operating expenses was 12% for the year ended December 31, 2023, and 17% for the year ended December 31, 2022. The percentages, excluding share-based compensation, were 12% for the year ended December 31, 2023, and 15% for the year ended December 31, 2022.

Critical Accounting Estimates

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.

While our significant accounting policies are more fully described in the notes to our financial statements appearing in this Annual Report on Form 10-K, we believe that the following accounting policies are the most critical to understanding and evaluating our reported financial results.

Share-Based Compensation

Stock-based awards are measured at fair value at each grant date. We recognize share-based compensation expenses ratably over the requisite service period of the option award.

Determination of the Fair Value of Share-Based Compensation Grants

The determination of the fair value of share-based compensation arrangements is affected by a number of variables, including estimates of the expected stock price volatility, risk-free interest rate and the expected life of the award. We value stock options using the Black-Scholes option-pricing model, which was developed for use in estimating the fair value of traded options that are fully transferable and have no vesting restrictions. Black-Scholes option-pricing model and other option valuation models require the input of highly subjective assumptions, including the expected stock price volatility. If we made different assumptions, our share-based compensation expenses, net loss, and net loss per common share could be significantly different. We determine that the fair value of common stock as the closing price of the Company's common stock as reported by NASDAQ on the option grant date.

The following summarizes the assumptions used for estimating the fair value of stock options granted during the periods indicated:

	Year Ended December 31,	
	2023	**2022**
Weighted-average grant date fair value per share	$ 2.89	$ 4.92
Expected volatility	80%-82%	82%-83%
Risk-free interest rate	3.3%-4.6%	1.5%-4.1%
Expected life (in years)	5.38–6.25	5.38–6.25
Dividend yield	—	—

With the exception of the dividend paid in 2021, we have assumed no dividend yield because we do not expect to pay dividends in the foreseeable future. The risk-free interest rate assumption is based on observed interest rates for U.S. Treasury securities with maturities consistent with the expected life of our stock options. The expected life represents the period of time the stock options are expected to be outstanding and is based on the simplified method when the stock option includes "plain vanilla" terms. Under the simplified method, the expected life of an option is presumed to be the midpoint between the vesting date and the end of the agreement term. We used the simplified method due to the lack of sufficient historical exercise data to provide a reasonable basis upon which to otherwise estimate the expected life of the stock options. For stock options that did not include "plain vanilla" terms, we used the contractual life of the stock option as the expected life. Such stock options consisted primarily of options issued to our board of directors that were immediately vested at issuance. Expected volatility is based on historical volatilities for publicly traded stock of comparable companies over the estimated expected life of the stock options. The Company accounts for forfeitures as they occur rather than on an estimated basis.

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.

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.

Results of Operations

Revenue

Revenue during the years ended December 31, 2023, and 2022 are summarized as follows (in thousands):

	Year Ended December 31,	
	2023	**2022**
Revenue		
Manufacturing revenue	$ -	$ 4,010
Clinical Trial revenue	-	-
Total revenue	$ -	$ 4,010

We had not generated any revenue before the year 2020. Under the clinical manufacturing agreement with Janssen and the addendum, for the year ended December 31, 2022, we have recorded $4.0 million as manufacturing revenue.

Cost of Goods Sold

Cost of goods sold during the years ended December 31, 2023, and 2022 are summarized as follows (in thousands):

	Year Ended December 31,	
	2023	**2022**
Cost of goods sold		
Manufacturing cost	$ -	$ 651
Clinical trial cost	-	-
Total cost of goods sold	$ -	$ 651

We had not incurred any cost of goods sold before the year 2020.The manufacturing cost for the year ended December 31, 2022, represents period expense for manufacturing, quality assurance and quality control departments.

Expenses

Research and Development

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

	Year Ended December 31, 2023	2022	Increase (Decrease)	% Increase (Decrease)
Salaries and related expenses	$ 13,385	$ 10,534	$ 2,851	27%
Laboratory and manufacturing supplies	3,723	6,477	(2,754)	-43%
Clinical trials and sponsored research	5,380	2,047	3,333	163%
Share-based compensation	2,797	3,641	(844)	-23%
Other	7,563	8,845	(1,282)	-14%
Total	$ 32,848	$ 31,544	$ 1,304	4%

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 4% to $32.8 million for the year ended December 31, 2023 compared to $31.5 million for the year ended December 31, 2022. The rise was mainly due to the increase in clinical trials activities, related to the new study being initiated in the second quarter of 2023. The increase of salaries and related expenses was mainly due to the $4.5 million bonus to the Chief Executive Officer in June 2023 compared to the $3.8 million bonus in June 2022, in which 85% was allocated to research and development expenses in 2023 compared to 60% in 2022. In addition, the decrease of laboratory and manufacturing supplies was primary caused by a reduction in raw material purchasing for clinical trial drug manufacturing.

General and Administrative

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

	Year Ended December 31, 2023	2022	Increase (Decrease)	% Increase (Decrease)
Salaries and related expenses	$ 1,281	$ 2,494	$ (1,213)	-49%
Patent filing expense	691	540	151	28%
Share-based compensation	465	1,421	(956)	-67%
Professional fees	1,422	1,035	387	37%
Other	803	815	(12)	-1%
Total	$ 4,662	$ 6,305	$ (1,643)	-26%

General and administrative expenses decreased 26% to $4.7 million for the year ended December 31, 2023 compared to $6.3 million for the year ended December 31, 2022. The decrease was primarily driven by the salaries and related expenses. The bonus to the Chief Executive Officer in June 2023 was $4.5 million compared to the $3.8 million bonus in June 2022, in which 15% was allocated to general and administrative expenses in 2023 compared to 40% in 2022. Share-based compensation decreased $1.0 million mainly due to the termination of VP of Finance and HR in February 2023, which resulted in the forfeiture of unvested awards, and the stock option expense per share of new grants decreased compared to the expense of fully amortized grants. In addition, professional fees increased $0.4 million mainly caused by the service fees related to the tender offer in June 2023.

Other Income

The following table summarizes other income (in thousands):

	Year Ended December 31,	
	2023	**2022**
Interest income	$ 10,421	$ 3,823
Other income (expense)	883	(121)
Foreign exchange gain (loss)	1,893	(2,800)
Total	$ 13,197	$ 902

The interest income for the years ended December 31, 2023 and 2022 was mainly generated from the Company’s Canadian bank accounts and interest bearing time deposits. The other income during the year ended December 31, 2023 was primarily from American Stock Transfer & Trust Company, LLC in accordance with the terms outlined in the settlement agreement. Foreign exchange gain (loss) was due to the fluctuation between the US dollar and the Canadian dollar in the year ended December 31, 2023 compared to 2022.

Income Taxes

The Company’s income tax expense for the tax period ended December 31, 2023 of $0.2 million, was primarily driven by adjustments related to prior periods and current year uncertain tax positions. The Company's income tax benefit for the tax period ended December 31, 2022 of $0.7 million, was primarily driven by the estimated 2022 Canadian loss carrybacks to 2019. The Company expects to maintain its full valuation allowance in all jurisdictions during 2024.

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 December 31, 2023, 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. In July 2022, we purchased interest bearing time deposits in the amount of $59.5 million for a one-year term, and upon maturity in July 2023, both the principal amount and the accrued interest were returned. At December 31, 2023, we had cash and cash equivalents of $200.0 million as compared to cash and cash equivalents of $157.3 million at December 31, 2022. The following table summarizes our sources and uses of cash (in thousands):

Net cash (used in) provided by:	Year Ended December 31, 2022	2022
Operating activities	$ (18,725)	$ (14,824)
Investing activities	61,497	(63,892)
Financing activities	(9)	-
Effect of foreign exchange rate on cash and cash equivalents	(46)	(961)
Net change in cash and cash equivalents	$ 42,717	$ (79,677)

Operating Activities

During the years ended December 31, 2023 and 2022 net cash used in operating activities was $(18.7) million and $(14.8) million, respectively. Net cash used in the years ended December 31, 2023 and 2022 primarily resulted from our net losses, whereas for the year ended December 31, 2022 the company received $4 million in revenue from the clinical manufacturing agreement with Janssen and the addendum.

Investing Activities

During the years ended December 31, 2023 and 2022, our investing activities generated net cash of $61.5 million and used net cash of $63.9 million, respectively. In July 2022, we purchased interest bearing time deposits in the amount of $63.3 million. Upon maturity in July 2023, we obtained both the principal amount and the accrued interest.

Financing Activities

During the year ended December 31, 2023, our financing activities used net cash of $9 thousand. We purchased 3,561 shares of our common stock, at a price of $4.00 per share, for an aggregate cost of approximately $14 thousand. During the year ended December 31, 2023, employees exercised stock options to purchase 1,250 shares of our common stock for approximately $5 thousand in net proceeds.

We expect to continue to incur operating losses in the future. We do not expect to receive any additional revenue under the clinical manufacturing agreement with Janssen. Further, we may not receive any product revenue until a drug candidate has been approved by the FDA, EMA or similar regulatory agencies in other countries and successfully commercialized. As of December 31, 2023, our principal sources of liquidity were our cash and cash equivalents, which totaled approximately $200.0 million.

Based on our cash and liquid assets, we believe that our cash and liquid assets will provide us with sufficient financial resources to fund operations and meet our capital requirements and anticipated obligations as they become due.

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 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISKS

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required under this item.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Index to Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of XBiotech Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Xbiotech Inc. and subsidiaries (the "Company") as of December 31, 2023 and 2022, and the related consolidated statements of operations, comprehensive loss, shareholders' equity, and cash flows for the years then ended, and the related notes to the consolidated financial statements (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of their operations and their cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

Critical audit matters are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

/s/ Whitley Penn LLP

We have served as the Company's auditor since 2022.

Austin, Texas
March 15, 2024

XBiotech Inc.

Consolidated Balance Sheets
(in thousands, except share data)

	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 200,023	$ 157,306
Interest bearing time deposits	-	60,172
Accrued interest receivable	860	1,216
Income tax receivable	75	548
Prepaid expenses and other current assets	760	601
Total current assets	201,718	219,843
Property and equipment, net	24,897	26,260
Total assets	$ 226,615	$ 246,103
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	$ 2,516	$ 2,408
Accrued expenses	3,501	1,603
Income tax payable	83	55
Total current liabilities	6,100	4,066
Long-term liabilities:		
Income tax payable	1,669	1,576
Deferred tax liability	-	59
Total liabilities	7,769	5,701
Shareholders' equity:		
Preferred stock, no par value, unlimited shares authorized, no shares outstanding	-	-
Common stock, no par value, unlimited shares authorized, 30,436,964 and 30,439,275 shares outstanding at December 31, 2023 and December 31, 2022, respectively	271,152	267,325
Accumulated other comprehensive income	-	826
Accumulated deficit	(52,306)	(27,749)
Total shareholders' equity	218,846	240,402
Total liabilities and shareholders' equity	$ 226,615	$ 246,103

See accompanying notes to consolidated financial statements.

XBiotech Inc.

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

	Year Ended December 31, 2023	2022
Revenue:		
Manufacturing revenue	$ -	$ 4,010
Total revenue	-	4,010
Cost of goods sold:		
Manufacturing cost	-	651
Total cost of goods sold	-	651
Gross margin	-	3,359
Operating expenses:		
Research and development	32,848	31,544
General and administrative	4,662	6,305
Total operating expenses	37,510	37,849
Loss from operations	(37,510)	(34,490)
Other income:		
Interest income	10,421	3,823
Other income (expense)	883	(121)
Foreign exchange gain (loss)	1,893	(2,800)
Total other income	13,197	902
Loss before income taxes	(24,313)	(33,588)
Income tax (expense) benefit	(244)	688
Net loss	$ (24,557)	$ (32,900)
Net loss per share—basic	$ (0.81)	$ (1.08)
Shares used to compute basic net loss per share	30,438,459	30,439,275
Net loss per share—diluted	$ (0.81)	$ (1.08)
Shares used to compute diluted net loss per share	30,438,459	30,439,275

See accompanying notes to consolidated financial statements.

XBiotech Inc.

Consolidated Statements of Comprehensive Loss
(in thousands)

	Year Ended December 31,	
	2023	**2022**
Net loss	$ (24,557)	$ (32,900)
Realized comprehensive income	-	(1,567)
Foreign currency translation adjustment	(252)	422
Reclassification of deferred tax assets	(574)	-
Comprehensive loss	$ (25,383)	$ (34,045)

See accompanying notes to consolidated financial statements.

XBiotech Inc.

Consolidated Statements of Shareholders' Equity
(in thousands)

	Number of Shares	Common Stock Amount	Accumulated Other Comprehensive Income	Retained Earnings (Accumulated deficit)	Total
Balance at December 31, 2021	30,439	$ 262,263	$ 1,971	$ 5,151	$ 269,385
Net loss	-	-	-	(32,900)	(32,900)
Foreign currency translation adjustment	-	-	422	-	422
Realized comprehensive income	-	-	(1,567)	-	(1,567)
Share-based compensation expense	-	5,062	-	-	5,062
Balance at December 31, 2022	30,439	267,325	826	(27,749)	240,402
Net loss	-	-	-	(24,557)	(24,557)
Tender offer	(4)	(14)	-	-	(14)
Foreign currency translation adjustment	-	-	(252)	-	(252)
Reclassification of deferred tax assets	-	574	(574)	-	-
Issuance of common stock under stock option plan	1	5	-	-	5
Share-based compensation expense	-	3,262	-	-	3,262
Balance at December 31, 2023	30,436	$ 271,152	$ -	$ (52,306)	$ 218,846

See accompanying notes to consolidated financial statements.

XBiotech Inc.

Consolidated Statements of Cash Flows
(in thousands)

	Year Ended December 31, 2023	2022
Operating activities		
Net loss	$ (24,557)	$ (32,900)
Adjustments to reconcile net loss to net cash (used in) operating activities:		
Depreciation	1,744	2,614
Foreign exchange (gain) loss	(1,893)	2,800
Share-based compensation expense	3,262	5,062
Changes in operating assets and liabilities:		
Income tax receivable	473	8,556
Accrued interest receivable	356	(1,216)
Prepaid expenses and other current assets	(160)	334
Accounts payable	91	357
Accrued expenses	1,895	229
Income tax payable	123	155
Deferred tax liability	(59)	(815)
Net cash (used in) provided by operating activities	(18,725)	(14,824)
Investing activities		
Purchase of property and equipment	(362)	(585)
Proceeds from maturity (purchases of) interest bearing time deposits	61,859	(63,307)
Net cash provided by (used in) investing activities	61,497	(63,892)
Financing activities		
Cash paid in tender offer	(14)	-
Issuance of common stock under stock option plan	5	-
Net cash used in financing activities	(9)	-
Effect of foreign exchange rate on cash and cash equivalents	(46)	(961)
Net change in cash and cash equivalents	42,717	(79,677)
Cash and cash equivalents, beginning of year	157,306	236,983
Cash and cash equivalents, end of year	$ 200,023	$ 157,306
Supplemental Information:		
Purchases of property and equipment in accounts payable	$ 19	$ 18

See accompanying notes to consolidated financial statements.

1. Organization

XBiotech Inc. ("XBiotech" or the "Company") was incorporated in Canada on March 22, 2005. The Company's headquarters are located in Austin, Texas. 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. XBiotech Germany GmbH was dissolved in February 2023.

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 $750 million in cash and up to $600 million in potential milestone payments (the "Janssen Transaction"). On February 2, 2022, XBiotech announced an addendum to the 2019 Janssen Manufacturing Agreement. XBiotech continued to manufacture Bermekimab for use by Janssen in its clinical trials through November 2022. 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. The Company's True Human™ antibody discovery technology has been used to identify new IL-1a targeting product candidates and has already brought one such candidate into a clinical studies in oncology and rheumatology; and another anti-IL-1a antibody into a Phase I study in neurology. While the Company previously was focused on a single True Human™ antibody targeting IL-1a, it is now developing more than one product candidate that targets IL-1a to be used in different areas of medicine.

The Company is subject to a number of risks common to companies in clinical stage 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 $200.0 million at December 31, 2023, will enable the Company to achieve several major inflection points, including completion of clinical studies with lead product candidates. The Company expects to have sufficient cash through at least 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 U.S. Generally Accepted Accounting Principles ("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 December 31, 2023 and 2022, the results of its operations and comprehensive loss for the years ended December 31, 2023, and 2022, and the cash flows for the years ended December 31, 2023, and 2022.

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 recognized 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 generated revenue through November 2022. While these agreements are not considered contracts with a customer based on the terms thereof, the Company has applied the revenue recognition guidance by analogy.

XBiotech is still in the research and development phase. 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 was not a customer, as these services are not the output of XBiotech's ordinary activities, the Company evaluated the terms of the agreements and 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 had a Clinical Manufacturing Agreement that it accounted for by analogy to ASC 606. In 2022 the Company executed a new manufacturing agreement with a Janssen related company. The agreement generated $4.0 million in revenue through termination in November 2022.

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 that 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

In December 2023, the FASB issued ASU 2023-09, "Income Taxes (Topic 740): Improvements to Income Tax Disclosures" ("ASU 2023-09"), which enhances the transparency and decision usefulness of income tax disclosures. Adjustments to the annual disclosure of income taxes include: (1) A tabular rate reconciliation comprised of eight specific categories, (2) Incomes taxes paid, disaggregated between significant federal, state, and foreign jurisdictions, (3) Eliminates requirements to disclose the nature and estimate of reasonably possible changes to unrecognized tax benefits in the next 12 months or that an estimated range cannot be made, and (4) Adds a requirement to disclose income (or loss) from continuing operations before income tax expense (or benefit) and income tax expense (or benefit) from continuing operations disaggregated between domestic and foreign. The ASU is effective for public business entities for fiscal years beginning on or after December 15, 2024 with early adoption permitted. The amendments in ASU 2023-09 should be applied on a prospective basis and retrospective application is permitted. The Company is in the process of evaluating the impact of adoption of ASU 2023-09 on the Company's consolidated financial statements and disclosures.

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 measures 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, 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 years ended December 31, 2023, and 2022 was included in the following line items on the consolidated statements of operations (in thousands).

	Year Ended December 31,	
	2023	2022
Research and development	$ 2,797	$ 3,641
General and administrative	465	1,421
Total share-based compensation expense	$ 3,262	$ 5,062

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

	Year Ended December 31,	
	2023	2022
Weighted-average grant date fair value per share	$ 2.89	$ 4.92
Expected volatility	80%-82%	82%-83%
Risk-free interest rate	3.3%-4.6%	1.5%-4.1%
Expected life (in years)	5.38–6.25	5.38–6.25
Dividend yield	-	-

Cash and Cash Equivalents

The Company considers highly liquid investments with a maturity of 90 days 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 Deposits

As of December 31, 2022, the Company held guaranteed investment certificates from a financial institution. The guaranteed investment certificates had a 12-month term at origination with interest payable at maturity. The Company obtained both the principal amount and accrued interest in July 2023 upon 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.

Fair Value Measurements

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

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

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

At December 31, 2023 and 2022, 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 consolidated balance sheets for cash and cash equivalents, interest bearing time deposits, prepaid expenses and other current assets, accounts payable, and accrued expenses approximate their fair values at December 31, 2023 and 2022, 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 using the straight-line method over the estimated useful lives of the assets, with the exception of land and construction in process which are not depreciated. The useful lives are as follows:

- Furniture and fixtures 7 years
- Office equipment 5 years
- 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. The 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 December 31, 2023.

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 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 Income/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.

Recent Accounting Pronouncements

Recently Issued Accounting Pronouncements

In June 2016, the Financial Accounting Standard Board ('FASB") issued Accounting Standards Update ("ASU" or "standard") No. 2016-13, Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments. Subsequently, the FASB issued several clarifying standard updates to clarify and improve the ASU. These ASUs significantly change how entities will measure credit losses for most financial assets and certain other instruments that are not measured at fair value through net income. The most significant change in this standard is a shift from the incurred loss model to the expected loss model that will be based on an estimate of current expected credit loss ("CECL"). Under the standard, disclosures are required to provide users of the financial statements with useful information in analyzing an entity's exposure to credit risk and the measurement of credit losses. The Company adopted the standard effective January 1, 2023. The impact of the adoption was not considered material to the consolidated financial statements.

3. Revenue

On February 2, 2022, the Company announced an addendum to the 2019 Janssen Manufacturing Agreement XBiotech continued to manufacture Bermekimab for use by Janssen in its clinical trials through November 2022. For the year ended December 31, 2022, the Company recorded $4.0 million of revenues, under the February 2022 agreement. The agreement was terminated in November 2022.

4. Property and Equipment and Building Construction in Progress

Property and equipment consisted of the following as of December 31, 2023 and 2022 (in thousands):

	2023	**2022**
Computer and office equipment	$ 279	$ 274
Furniture and fixtures	129	129
Land	1,418	1,418
Scientific equipment	16,367	16,059
Vehicle	112	112
Building	24,173	24,173
Mobile facility	189	189
Construction in process	469	401
Accumulated depreciation	(18,239)	(16,495)
	$ 24,897	$ 26,260

Depreciation expenses related to property and equipment amounted to approximately $1.7 million and $2.6 million, for the years ended December 31, 2023, and 2022, respectively. Construction in process is related to research and development and manufactory equipment. Depreciation expense is recorded to research and development and general and administrative expense line items on the Consolidated Statements of Operations (in thousands).

5. Accrued Expenses

Accrued expenses consist of the following as of December 31, 2023, and 2022 (in thousands):

	2023	2022
Accrued compensation and related expenses	$ 562	$ 489
Accrued professional fees	52	117
Accrued clinical trial expenses	2,826	928
Other	61	69
	$ 3,501	$ 1,603

6. Common Stock

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

On May 17, 2023, XBiotech announced that it had commenced a "modified Dutch auction" tender offer to purchase up to $80.0 million of its common shares, or such lesser number of common shares as are properly tendered and not properly withdrawn, at a price not less than $3.80 nor greater than $4.00 per common share, to the seller in cash. The tender offer expired on June 15, 2023.

On June 20, 2023, the Company announced the final results of its "modified Dutch Auction" tender offer. The Company accepted for purchase 3,561 shares of its common stock, at a price of $4.00 per share, for an aggregate cost of approximately $14 thousand, excluding fees and expenses related to the tender offer. These shares represented an immaterial percent of the shares outstanding. The repurchased shares were retired and have been classified to reduce common stock in the accompanying consolidated balance sheet as of December 31, 2023.

During the year ended December 31, 2023, 1,250 shares of common stock were issued upon the exercise of stock options at a price of $3.84 per share for total proceeds of $4,800.

No stock options were exercised from January 1, 2022 through December 31, 2022.

7. 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' expiration 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	152,600	3.65-11.25	7.07
Exercised	-	-	-
Forfeitures	(250,375)	3.27-21.74	12.31
Options outstanding at December 31, 2022	4,558,902	$2.71-$21.74	$ 10.47
Granted	809,600	3.38-6.04	4.12
Exercised	(1,250)	3.84	3.84
Forfeitures	(327,734)	3.84-19.09	10.43
Options outstanding at December 31, 2023	5,039,518	$2.71-$21.74	$ 9.46

The weighted average fair value of the options issued to directors, employees and consultants during the fiscal years ended December 31, 2023, and 2022, was $2.89 and $4.92, respectively. The total intrinsic value of options exercisable and total options outstanding at December 31, 2023 was $2.2 million and $4.1 million. The total intrinsic value of options exercisable and total options outstanding at December 31, 2022 was immaterial. The total fair value of options vested during the years ended December 31, 2023, and 2022 was $3.5 million, and $5.6 million, respectively.

A summary of the activity in the Company's nonvested shares is as follows:

	Year Ended December 31,			
	2023		2022	
	Shares	Weighted Average Granted Date Fair Value	Shares	Weighted Average Granted Date Fair Value
Nonvested at January 1,	429,950	8.25	1,131,458	8.59
Granted during the period	809,600	2.89	152,600	4.92
Vested during the period	(569,100)	6.17	(716,491)	7.86
Forfeited during the period	(98,025)	5.14	(137,617)	9.40
Nonvested at end of period	571,925	2.40	429,950	8.25

As of December 31, 2023, there was approximately $1.4 million of unrecognized compensation cost, related to stock options granted under the Plan which will be amortized to stock compensation expense over the next 1.1 years. The weighted-average remaining contractual term of outstanding options as of December 31, 2023 is 5.39 years. Total exercisable stock options as of December 31, 2023 is 4.5 million. The weighted-average exercise price of options exercisable as of December 31, 2023 is $10.07 per share and the weighted-average remaining contractual term is 4.93 years.

8. Net Loss Per Share

The following summarizes the computation of basic and diluted net income(loss) per share for the years ended December 31, 2023, and 2022 (in thousands, except share and per share data):

	Year Ended December 31,	
	2023	2022
Net loss	$ (24,557)	$ (32,900)
Weighted-average number of common shares—basic	30,438,459	30,439,275
Net loss per share—basic	$ (0.81)	$ (1.08)
Weighted-average number of common shares—diluted	30,438,459	30,439,275
Net loss per share—diluted	$ (0.81)	$ (1.08)

The following potentially dilutive securities outstanding, prior to the use of the treasury stock method or if-converted method, have been excluded from the computation of diluted weighted-average common shares outstanding, because including them would have had an anti-dilutive effect due to the losses reported.

	Year Ended December 31,	
	2023	2022
Stock options	5,039,518	4,558,902

9. Income Taxes

The components of income before income taxes are as follows (in thousands):

	Years Ended December 31,	
	2023	2022
United States	$ (27,144)	$ (28,161)
Foreign	2,831	(5,427)
Total	$ (24,313)	$ (33,588)

The components of the provision for income taxes are as follows for the years ended December 31, 2023, and 2022 (in thousands):

Current	2023	2022
United States	$ 130	$ 457
Foreign	173	(329)
Total	303	128
Deferred		
United States	-	-
Foreign	(59)	(816)
Total	(59)	(816)
Total income tax expense (benefit)	$ 244	$ (688)

The provision for income taxes differs from the amount computed by applying the Canada statutory rate to pre-tax income as follows for the years ended December 31, 2023, and 2022:

	2023	2022
Income tax benefit computed at federal tax rate	27.0%	27.0%
Foreign operations	(5.4)%	(4.1)%
Change in valuation allowance	(26.1)%	(14.6)%
Tax credits generated	8.6%	3.5%
Prior year adjustments	(2.3)%	0.4%
Changes in uncertain tax positions	(0.4)%	(0.3)%
Foreign exchange gain and loss	2.1%	(1.6)%
Stock compensation	(2.4)%	(2.3)%
Non-deductible compensation	(6.8)%	(5.8)%
Foreign Liquidation	4.5%	0.0%
Other	0.3%	(0.2)%
Total	(1.0)%	2.0%

The effective tax rate for the year ended December 31, 2023 varied from the Canadian statutory rate primarily due to losses in jurisdictions for which a valuation allowance is recorded and a benefit may not be recognized. The effective tax rate for the year ended December 31, 2022 varied from the Canadian statutory rate primarily due to losses in jurisdictions for which a valuation allowance is recorded and a benefit may not be recognized, a shift in income between jurisdictions related to certain transfer pricing adjustments which impacted the benefit associated with available loss carrybacks, and non-deductible compensation.

The tax effect of temporary differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases that give rise to deferred tax assets and liabilities is as follows:

	2023	2022
Net operating loss carryforwards	$ 1,288	$ -
Research and other credits	5,851	3,820
Stock based compensation	2,530	2,703
Capitalized research expenses	7,800	5,210
Share issuance costs	39	229
Accrued liabilities	696	294
Foreign exchange	-	687
Deferred tax assets before valuation allowance	18,204	12,994
Valuation allowance	(17,576)	(11,225)
Deferred tax assets	628	1,719
Depreciation	535	710
Prepaid assets	93	93
Uncollectible debts	-	975
Deferred tax liability	628	1,777
Net deferred tax asset (liability)	$ -	$ (59)

For the year ended December 31, 2023, the Company has a USA federal net operating loss carryforward of $6.2M which will carryforward indefinitely. The Company has $6.6M of USA federal research and development tax credits carryforwards which are presented in the financial statements net of $1.4M of related uncertain tax positions, which will begin to expire in 2037. In addition, the Company has $0.8M of Texas research and development tax credits carryforwards which are presented in the financial statements net of $0.2M of related uncertain tax positions, which will begin to expire in 2042. Also, after weighing all available and positive and negative evidence the Company determined a full valuation allowance for all jurisdictions was necessary.

For the year ended December 31, 2023, the Company has not recorded any outside basis difference deferreds given its intention to indefinitely reinvest earnings from its foreign operations. In addition, given the Company's estimated outside tax basis in its USA investment is in excess of book basis, there is no unrecognized deferred tax liability.

The Company is subject to income tax in multiple jurisdictions, including Canada, USA, and the state of Texas. The Company has Canadian, USA, and Texas income tax returns that are open to examination for the 2020, 2020, and 2019 tax years, respectively. In addition, the utilization of tax carryforwards, from periods prior to those previously mentioned may also be audited by the taxing authorities once utilized. As a result, the Company continuously monitors its current and prior filing positions in order to determine if any unrecognized tax positions need to be recorded. The analysis involves considerable judgement and is based on the best information available. A reconciliation of the beginning and ending amount of unrecognized tax benefits as of December 31, 2023 and 2022 are as follows (in thousands):

	2023	2022
Balance as of January 1	$ 2,864	$ 2,389
Additions based on tax positions related to the current year	389	130
Additions for tax positions of prior years	260	346
Reductions for tax positions of prior years	(4)	-
Settlements & statute of limitations	(536)	-
Balance at December 31	$ 2,973	$ 2,864

The Company recognized interest and penalties related to unrecognized tax benefits of $93 thousand and $63 thousand as a component of income tax expense for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023 and 2022, there are $1.7M and $1.6M, respectively, of unrecognized tax benefits that if recognized would affect the annual effective tax rate. In addition, it is reasonably possible that approximately $0.1M of the unrecognized tax benefits may be recognized in the next 12 months as a result of a lapse of the statute of limitations. No other positions are expected to significantly decrease within the next 12 months.

10. Subsequent Event

On January 3, 2024, the Company entered into a Convertible Loan Agreement (the “Loan”) with John Simard, the Company’s Founder, President, Chief Executive Officer and Chairman. The Loan provides $10 million in immediate funding for the construction of a new, state-of-the-art research and development facility at the Company's property at 5217 Winnebago Lane in Austin, Texas. The Loan is secured by the real estate and cash holdings of the Company, with interest to accrue at a simple rate equal to eight percent per year and interest-only payments to be made at six-month intervals after the Loan is funded. At Mr. Simard’s election, the balance may be converted to XBiotech stock at any time the Loan balance is outstanding at a fixed conversion price equal to the average Nasdaq Official Closing Price of the common stock (as reflected on Nasdaq.com) for the five trading days immediately preceding the signing of this Agreement, which is $4.048 per share. The conversion feature is subject to a 19.9% cap limiting the number of shares that could be converted under the Agreement based on Mr. Simard’s total stock ownership in the Company at the time of conversion. The Loan also allows Mr. Simard to obtain immediate cash repayment of the Loan balance at his election one year after the loan is funded or upon certain other conditions set forth in the Loan. The Loan was negotiated, evaluated, and approved on behalf of the Company by a committee of independent and disinterested directors.

11. Selected Quarterly Financial Data (Unaudited)

Selected Quarterly Financial Data (Unaudited) for the years ended December 31, 2023 and 2022 is presented below (in thousands except per share data):

2023	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Loss from operations	$ (7,145)	$ (13,258)	$ (8,520)	$ (8,588)
Net loss	(3,816)	(8,742)	(7,364)	(4,635)
Net loss per share—basic and diluted	(0.13)	(0.29)	(0.24)	(0.15)

2022	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Loss from operations	$ (7,845)	$ (12,094)	$ (6,389)	$ (8,162)
Net loss	(5,395)	(11,644)	(12,658)	(3,203)
Net loss per share—basic and diluted	(0.18)	(0.38)	(0.42)	(0.10)

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. 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-K, 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, 2023, 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 year ended December 31, 2023 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.

ITEM 9B. OTHER INFORMATION

None.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

We incorporate by reference the information required by this Item with respect to directors and the Audit Committee from the information under the caption “ELECTION OF DIRECTORS,” including in particular the information under “Nominating and Corporate, Governance and Review Committee” , “Audit Committee”, “Report of the Audit Committee & the Board of Directors”, “Code of Ethics” and “Delinquent Section 16(a) Reports” and “EXECUTIVE OFFICERS” contained in our definitive Proxy Statement (the “Proxy Statement”), which we will file on or about April 28, 2024 with the Securities and Exchange Commission in connection with the solicitation of proxies for our 2024 Annual Meeting of Stockholders to be held on June 23, 2024.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated herein by reference to the information contained under the sections captioned “EXECUTIVE COMPENSATION”, “DIRECTOR COMPENSATION”, “Compensation Committee Interlocks and Insider Participation,” “Employment Arrangements” and “Compensation Committee Report” of the Proxy Statement.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item will be set forth under the heading “Security Ownership of Certain Beneficial Owners and Management" in our Proxy Statement and is incorporated herein by reference.

The information required by Item 201(d) of Regulation S-K will be set forth in the section headed “Equity Compensation Plan Information” in our Proxy Statement and is incorporated herein by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

The information required by this item will be set forth in the section headed "Transactions with Related Persons" in our Proxy Statement and is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item will be set forth in the section headed "Ratification of Selection of Independent Registered Public Accounting Firm" in our Proxy Statement and is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

Financial Statements

See Index to Consolidated Financial Statements under Item 8 of Part II.

Financial Statement Schedules

None

EXHIBIT INDEX

Exhibit Number	Description
2.1†	Asset Purchase Agreement, dated as of December 7, 2019, between XBiotech Inc. and Janssen Biotech, Inc. (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed on December 30, 2019)
3.1	Certificate of Continuation dated September 23, 2005, issued by the Registrar of Companies, Province of British Columbia, Canada (incorporated by reference to Exhibit 3.1 to the Company's Registration Statement on Form S-1 filed with the SEC on February 2, 2015)
3.2	Notice of Articles, dated December 8, 2005, issued by the Registrar of Companies, Province of British Columbia, Canada (incorporated by reference to Exhibit 3.2 to the Company's Registration Statement on Form S-1 filed with the SEC on February 2, 2015)
3.3	Articles of XBiotech Inc. (incorporated by reference to Exhibit 3.3 to the Company's Registration Statement on Form S-1/A filed with the SEC on March 27, 2015)
4.1	Description of Registrant's securities registered pursuant to Section 12 of the Securities Exchange Act of 1934(incorporated by reference to Exhibit 4.1 to the Annual Report on Form 10-K filed with the SEC on March 15, 2022)
10.1+	Executive Employment Agreement dated as of March 22, 2005 between XBiotech and John Simard (incorporated by reference to Exhibit 10.1 to the Company's Registration Statement on Form S-1 filed with the SEC on February 2, 2015)
10.2+	Change in Control Agreement dated as of March 22, 2005 between XBiotech and John Simard (incorporated by reference to Exhibit 10.2 to the Company's Registration Statement on Form S-1 filed with the SEC on February 2, 2015)
10.3	Confidentiality and Assignment of Inventions Agreement dated as of March 22, 2005 between XBiotech and John Simard (incorporated by reference to Exhibit 10.3 to the Company's Registration Statement on Form S-1 filed with the SEC on February 2, 2015)
10.4+	XBiotech 2005 Incentive Stock Option Plan (Restated) (incorporated by reference to Exhibit 4.4 to the Company's Registration Statement on Form S-8 filed with the SEC on October 19, 2015)

10.5+	Form of indemnification agreement between XBiotech and each director of XBiotech (incorporated by reference to Exhibit 10.5 to the Company's Registration Statement on Form S-1 filed with the SEC on February 2, 2015)
10.6	Licensing Agreement dated January 16, 2015 between XBiotech USA, Inc. and Lonza Sales AG (portions of this exhibit have been omitted pursuant to a request for confidential treatment under Rule 406 of the Securities Act. incorporated by reference to Exhibit 10.9 to the Company's Registration Statement on Form S-1/A filed with the SEC on March 10, 2015)
10.7	Research and Collaboration Agreement dated December 15, 2014 by and between XBiotech USA, Inc. and the South Texas Blood & Tissue Center (portions of this exhibit have been omitted pursuant to a request for confidential treatment under Rule 406 of the Securities Act of 1933. incorporated by reference to Exhibit 10.10 to the Company's Registration Statement on Form S-1/A filed with the SEC on March 10, 2015)
10.8+	XBiotech Inc. 2015 Equity Incentive Plan (incorporated by reference to Exhibit 10.11 to the Company's Registration Statement on Form S-1/A filed with the SEC on March 10, 2015)
10.9+	Form of Incentive Share Option Agreement under the 2015 Equity Incentive Plan (incorporated by reference to Exhibit 10.9 to the Annual Report on Form 10-K filed with the SEC on March 15, 2023)
10.10+	Form of Nonqualified Share Option Agreement under the 2015 Equity Incentive Plan (incorporated by reference to Exhibit 10.10 to the Annual Report on Form 10-K filed with the SEC on March 15, 2023)
10.11+	Second Amendment to the XBiotech Inc. 2015 Equity Incentive Plan (incorporated by reference to Annex A to the Registrant's Definitive Proxy Statement on Schedule 14A filed on April 29, 2020)
10.12+	Third Amendment to the XBiotech Inc. 2015 Equity Incentive Plan (incorporated by reference to Annex B to the Registrant's Definitive Proxy Statement on Schedule 14A filed on April 29, 2020)
10.13+*	Board Member Agreement, dated as of February 27, 2018, by and between XBiotech Inc. and Jan-Paul Waldin (incorporated by reference to Exhibit 10.13 to the Annual Report on Form 10-K filed with the SEC on March 15, 2023)
10.14+*	Board Member Agreement, dated as of March 20, 2018, by and between XBiotech Inc. and Donald H. MacAdam (incorporated by reference to Exhibit 10.14 to the Annual Report on Form 10-K filed with the SEC on March 15, 2023)
10.15+	Board Member Agreement, dated as of July 10, 2019, by and between XBiotech Inc. and Peter Libby (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on July 16, 2019)
10.16†	IP Non-Assertion and License Agreement, dated as of December 30, 2019, between XBiotech Inc. and Janssen Biotech, Inc. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on December 30, 2019)
10.17†	Clinical Manufacturing Agreement, dated as of December 30, 2019, between XBiotech Inc. and Janssen Biotech, Inc. (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on July 16, 2019)
10.18†	Transition Services Agreement, dated as of December 30, 2019, between XBiotech Inc. and Janssen Biotech, Inc. (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K filed on July 16, 2019)

21.1*	List of subsidiaries
23.1*	Consent of Independent Registered Public Accounting Firm, Whitley Penn LLP
31.1*	Certification of the Principal Executive Officer Required Under Rules 13a-14(a) and 15d-14(a) of the Securities Act of 1934, as amended, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of the Principal Financial Officer Required Under Rules 13a-14(a) and 15d-14(a) of the Securities Act of 1934, as amended, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1**	Certification of Chief Executive Officer pursuant to18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2**	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
97	XBiotech Inc. Clawback Policy
101*	The following financial statements from the XBiotech Inc. Annual Report on Form 10-K for the year ended December 31, 2023, formatted in Inline Extensive Business Reporting Language (XBRL): (i) consolidated balance sheets, (ii) consolidated statements of operations, (iii) consolidated statements of comprehensive loss, (iv) consolidated statements of shareholders' equity; (v) consolidated statements of cash flows and (vi) notes to consolidated financial statements (detail tagged).
104*	Cover Page Interactive Data File (embedded within the inline iXBRL document and contained in Exhibit 101).
†	Certain identified information has been excluded from this exhibit because the Company does not believe it is material and is the type that the Company customarily treats as private and confidential. Redacted information is indicated by [*****]. The Company hereby agrees to furnish a copy of any omitted schedule or attachment to the Securities and Exchange Commission upon request.
+	Indicates management contract or compensatory plan
*	Filed herewith
**	Exhibits 32.1 and 32.2 shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, or otherwise subject to the liability of that Section. Such exhibits shall not be deemed incorporated by reference into any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934.

ITEM 16. FORM 10–K SUMMARY

Not applicable.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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 on March 15, 2024.

XBIOTECH INC.,

/s/ JOHN SIMARD
Name: John Simard
Title: President and Chief Executive Officer
(Principal Executive Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature and Title	Date
/s/ JOHN SIMARD John Simard, Chief Executive Officer (Principal Executive Officer) and Director	March 15, 2024
/s/ ANGELA HU Angela Hu, Principal Financial Officer and Principal Accounting Officer	March 15, 2024
/s/ W. THORPE MCKENZIE W. Thorpe McKenzie, Director	March 15, 2024
/s/ JAN-PAUL WALDIN Jan-Paul Waldin, Director	March 15, 2024
/s/ DONALD MACADAM Donald MacAdam, Director	March 15, 2024
/s/ PETER LIBBY Peter Libby, Director	March 15, 2024

Exhibit 21.1

LIST OF SUBSIDIARIES

Name	Country
XBiotech USA, Inc. (Delaware)	United States
XBiotech Germany GmbH	Germany

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on Form S-8 (File Nos. 333-207476 and 333-249288) of our report dated March 15, 2024 relating to the consolidated financial statements of XBiotech Inc. and subsidiaries appearing in this Annual Report on Form 10-K of XBiotech Inc. and subsidiaries for the year ended December 31, 2023.

/s/ Whitley Penn LLP
Austin, Texas
March 15, 2024

Exhibit 31.1

CERTIFICATIONS

I, John Simard, certify that:

1. I have reviewed this annual report on Form 10-K 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: March 15, 2024

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

Exhibit 31.2

CERTIFICATIONS

I, Angela Hu, certify that:

1. I have reviewed this annual report on Form 10-K 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: March 15, 2024

/s/Angela Hu
Angela Hu
Director of Finance
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION 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 Annual Report of XBiotech Inc. on Form 10-K for the period ended December 31, 2023 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: March 15, 2024

Exhibit 32.2

CERTIFICATION 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 Annual Report of XBiotech Inc. on Form 10-K for the period ended December 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Angela Hu, Principal Financial Officer and Principal Accounting Officer 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/ Angela Hu
Angela Hu
Director of Finance
(Principal Financial Officer)
Date: March 15, 2024

XBIOTECH INC.
CLAWBACK POLICY

Definitions

For purposes of this policy, the following definitions shall apply:

- "Accounting Restatement" means an accounting restatement due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

- "Erroneously Awarded Compensation" means the amount of Incentive-Based Compensation Received by an Executive Officer that exceeds the amount of Incentive-Based Compensation that otherwise would have been Received had it been determined based on the restated amounts, which amount must be computed without regard to any taxes paid by such Executive Officer.

- "Executive Officer" means the Company's president, chief executive officer, principal financial officer, principal accounting officer (or if there is no such accounting officer, the controller), any vice-president of the issuer in charge of a principal business unit, division or function, any other officer who performs a policy-making function, or any other person who performs similar policy-making functions for the issuer. Executive Officers for purposes of this policy includes, at a minimum, such executive officers identified as such in the Company's Annual Report on Form 10-K.

- "Financial Reporting Measure" are measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measures that are derived wholly or in part from such measures. Stock price and total shareholder return are also Financial Reporting Measures. A Financial Reporting Measure need not be presented within the financial statements or included in a filing with the U.S. Securities and Exchange Commission.

- "Incentive-Based Compensation" means any compensation that is granted, earned or vested based wholly or in part upon the attainment of any Financial Reporting Measure.

- "Received" with respect to Incentive-Based Compensation means the fiscal period during which the Financial Reporting Measure specified in the Incentive-Based Compensation award is attained, even if the payment or grant of the Incentive-Based Compensation occurs after the end of that period.

- "Recovery Period" means the three (3) completed fiscal years immediately preceding the date that the Company is required to prepare an Accounting Restatement, which date is the earlier to occur of (a) the date the Board, a committee of the Board, or the officer or officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare an Accounting Restatement or (b) the date a court, regulator or other legally authorized body directs the Company to prepare an Accounting Restatement. In addition to these last three (3) completed fiscal years, the Recovery Period also applies to any transition period (that results from a change in the Company's fiscal year) within or immediately following those three (3) completed fiscal years. However, a transition period between the last day of the Company's previous fiscal year end and the first day of its new fiscal year that comprises a period of nine (9) to twelve (12) months would be deemed a completed fiscal year.

Policy Statement

In the event the Company is required to prepare an Accounting Restatement, then the Company will recover reasonably promptly the amount of Erroneously Awarded Compensation that is Received by any current or former Executive Officer during the Recovery Period.

Additionally, the Board, in its sole discretion and subject to applicable law, may seek to recover Incentive-Based Compensation or discretionary compensation Received by any current or former Executive Officer during the Recovery Period in the event that such Executive Officer willfully engaged in conduct which is demonstrably or materially injurious to the Company, monetarily or otherwise.

Exceptions

The Company will not be required to enforce this policy to the extent that the Compensation Committee (the "Committee") of the Board determines that (i) recovery would be impracticable and (ii) one of the conditions of (A), (B), or (C) are satisfied:

(A) The direct expense paid to a third party to assist in enforcing this policy would exceed the amount to be recovered; provided, before concluding that it would be impracticable to recover any amount of Erroneously Awarded Compensation based on expense of enforcement, the Company has made a reasonable attempt to recover such amounts, documented such reasonable attempt(s) to recover, and provided that documentation to NASDAQ.

(B) Recovery would violate home country law where that law was adopted prior to November 28, 2022; provided, that before concluding that it would be impracticable to recover any amount of Erroneously Awarded Compensation based on violation of home country law, the Company must obtain an opinion of home country counsel, acceptable to NASDAQ, that recovery would result in such a violation, and must provide such opinion to NASDAQ.

(C) Recovery would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to the Company's employees, to fail to meet the requirements of the Internal Revenue Code of 1986, as amended.

Prohibition on Indemnity or Reimbursement

The Company is prohibited from indemnifying any current or former Executive Officer against the loss of any Erroneously Awarded Compensation or paying or reimbursing such Executive Officers for insurance premiums to recover losses incurred under this policy.