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 19 | 34 |
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| For the fiscal year ended December 31, 2022 | |

☐ 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

Title of each class

N/A

Name of each exchange on which registered

(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:

Trading Symbol(s)

| 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, a non-accelerated filer, a smaller reporting company or an | | | | | |
| emerging growth company. See the definitions of "large company" in Rule 12b-2 of the Exchange Act. | accelerated filer," "accelerated filer," "sm | aller reporting company" and "emerging growth | | | |
| Large accelerated filer Accelerated file Accelerated file | er □ 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. \Box | | | | | |
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| 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. \Box | | | |
| 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 $\$240.10D-1(b)$. \Box | | | |
| Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes \Box No $oxtimes$ | | | |
| The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of June 30, 2022, was approximately \$132,808,406, 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 6,849,860 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, 2023, 30,439,275 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 2023 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," "could," "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.

ITEM 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 or otherwise engineered. It is intuitive that naturally occurring human antibodies have the potential to be safer, more effective and faster to develop than 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 manufacture 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 tissue breakdown, angiogenesis, the formation of blood clots, malaise, muscle wasting 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 HumanTM antibody therapeutic it was developing that targeted IL-1a for \$1.35 billion in cash and potential milestone payments. The unique deal structure had XBiotech agree not to further develop any anti-IL-1a antibodies only for dermatology, while XBiotech was permitted to continue to discover and develop new True HumanTM 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 and rheumatology. While the Company previously was focused on a single True HumanTM antibody targeting IL-1a, we are now developing in parallel two 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 partnership or sale of each antibody separately for different disease indications.

Financial

XBiotech received \$675 million on December 30, 2019 and \$75 million on June 30, 2021 from the sale of of its True Human™ antibody targeting IL-1a. In February 2020, XBiotech used approximately \$420 million to repurchase stock from its shareholders. In July 2021, XBiotech distributed \$75 million cash dividend to its shareholders. The remaining cash was reserved for ongoing operations as part of its multi-year business plan to identify and develop True Human™ antibodies, including anti-Il-1a therapies, aiming to commercialize these drug candidates.

Since January 1, 2020 XBiotech also used its proprietary manufacturing technology, its manufacturing plant and infrastructure to produce drug product for under a supply agreement. In addition, during 2020 and 2021 XBiotech provided clinical trial operations services for two Phase II clinical studies. In 2022 XBiotech executed a new manufacturing supply agreement to extend its production of the anti-IL-1a antibody it sold. We believe that XBiotech is in a very favorable position for an R&D stage biopharmaceutical company, with a strong cash position in its balance sheet related to sale of its drug candidate, the absence of debt, a robust pipeline and a remarkably modest burn rate.

Further Development of IL-1a Therapies

IL-1a plays a key role in many disease processes. While it is produced naturally by the body, when not properly controlled, 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 a myriad of scientific research have shown that blocking IL-1a may have a beneficial effect in some or most of these medical conditions. The potential unmet medical need for blocking IL-1a is therefore very significant. In 2021, the Company entered the clinic with a molecule targeting IL-1 α in oncology (Pancreatic Cancer). The Company has also started its clinical program in Rheumatology; and has filed an investigational new drug application for a stroke treatment.

Because the potential medical use for anti-IL-1a therapy is so large, the Company is developing more than one True HumanTM antibody, each neutralizing IL-1a, but designating different antibodies for use in specific areas of medicine. This will potentially allow XBiotech to individually partner different antibodies according to unique medical areas. The Company expects this will diversify risk for anti-IL-1a therapies, allow multiple partnerships, maximize value and facilitate greater resource dedication to these True HumanTM therapeutics.

Infectious Disease Pipeline

XBiotech continued to achieve significant milestones with its infectious disease pipeline in 2021. The Company has identified several major areas of urgent unmet medical need for True Human™ anti-infective antibody therapies. True Human™ antibodies may be used therapeutically or prophylactically to supplement immunity in individuals where the robustness of the immune system has declined, such as in the elderly or individuals taking immunosuppressive drugs (ie. methotrexate). The Company is confident that Ture Human antibodies can be a highly effective means for providing protection against numerous related infectious diseases, such as shingles or influenza. Donations from blood banks are screened for healthy antibodies that have exceptionally strong natural immunity to specific diseases. True Human™ antibodies are derived only from donors with the best disease fighting antibodies in the population.

True Human™ antibodies may also be used to provide highly potent and targeted immunity against infectious diseases in young, otherwise healthy individuals, where infectious agents have overwhelmed natural immunity. For example, this can occur during intravenous drug use, from a deep puncture wound, or from the result of surgery, where bacteria has gained unnatural entry into a body compartment where it can establish and evade the immune system. Staphylococcus aureus, including the deadly methicillin resistant (MRSA) variant, is an example of our candidate anti-infective therapeutics.

Another patient population where True HumanTM antibodies may be particularly useful is in infants. Prior to developing strong immunity, infants can be vulnerable to infections. Particularly premature infants may need supplemental immunity against specific infectious agents, such as respiratory syncytial virus (RSV). In 2022, the Company continued making progress in its search for a True HumanTM antibody therapeutic candidate for RSV.

We believe True Human™ antibody therapies have a very important application in the case of potent viruses, such as influenza, where the aggressive nature of the virus takes even relatively strong immune systems to the limits. Here again, in elderly, the young or those with weakened immune systems, an aggressive virus like influenza can be life threatening. XBiotech has developed an antibody cocktail that is capable of neutralizing all known forms of influenza—from the deadly 1918 strain to the most recent versions of flu. On its research campus, XBiotech has a fully dedicated infectious disease and animal facility laboratory. The facility is just a short walk from the Company's main manufacturing headquarters and incorporates an animal biological safety level 2 (ABSL2) infectious disease laboratory for testing the Company's True Human™ antibodies against infectious disease targets.

Infrastructure

In 2022 XBiotech completed its expansion of its manufacturing and R&D center. The expansion resulted in the creation of two new wings: one provides state-of-the-art wet laboratory research benches 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. XBiotech owns its 48-acre campus—and all structures on the property—debt-free.

A Background on Therapeutic Antibodies

A century ago, scientists and physicians envisioned being able to custom design therapeutic "antibodies" that were highly specific for a single target. By selectively attacking disease while sparing healthy tissue, these "magic bullets" were anticipated to be ideal therapeutic agents. It was not until the early 1970's, however, that this vision was realized when Kohler and Milstein developed a ground-breaking method for making target-specific monoclonal antibodies—a Nobel prize-winning endeavor. Using this new approach, numerous monoclonal antibody-based research, diagnostic, and therapeutic products developed.

Kohler and Milstein's discovery was based on their knowledge that the immune system of higher animals produces antibodies as a method of protecting them from various harmful agents, such as viruses, bacteria, and diseased cells. White blood cells, known as B cells, produce billions of different types of antibodies, each with a unique potential to bind and neutralize different disease targets. The vast array of possible treatments based on antibodies led to the development of what is now a major industry around the use of therapeutic antibodies.

True HumanTM Antibodies

White blood cells in the human body secrete billions of different antibodies that circulate through the blood to react and protect us from toxins, infectious agents or even other unwanted substances produced by our body. True HumanTM antibodies, as the name implies, are simply those that are derived from a natural antibody identified from the blood of an individual. To develop a True HumanTM antibody therapy, donors are screened to find an individual that has a specific antibody that matches the desired characteristics needed to obtain the intended medical benefit. White blood cells from that individual are obtained, the unique gene that produced the antibody is cloned, and the genetic information is used to produce an exact replica of the antibody sequence. A True HumanTM antibody is, therefore, not to be confused with other marketed antibodies, such as so-called "fully human" antibodies—where antibody reactivity is developed through gene sequence engineering in the laboratory.

Fundamental Science of True Human™ Antibodies

To appreciate the background safety and tolerability of True Human $^{\text{TM}}$ antibodies, it is important to consider the fundamental biology of natural antibody production.

Billions of different white blood cells secrete billions of unique antibodies every day into circulation. The vast number of different antibodies (and cells that produce them), are essential to enable adequate molecular diversity to ward off a vast range of potential infectious or toxic threats. In other words, since antibodies act to bind and thereby neutralize unwanted agents, any given circulating antibody must be able to react with a potentially limitless number of existing or evolving disease entities.

The staggering number of different antibodies needed to achieve this level of preparedness, however, is a daunting concept from a genetics point of view. If an individual antibody gene was needed to encode each of a billion different antibodies, there would be approximately 20,000 times as many genes needed just for antibodies as there would be needed to encode the rest of the entire human genome. Individual cells would need to be gigantic, and monumental resources of the body would be required to make, copy and maintain all of the DNA. Clearly, the system of antibodies could not have evolved to protect us, had not an elegant solution emerged to deal with this genetic conundrum.

Thus, a hallmark of the immune physiology of all vertebrates (all have antibodies) is the ability to recombine and selectively mutate a relatively small number of gene segments to create a phenomenal and effectively unlimited number of antibody genes. By rearranging, recombining and mutating the genetic code, specialized white blood cells, or B lymphocytes, are able to create an unlimited array of antibody genes. The consequence of this genetic engineering, however, is that each antibody gene is unique to the individual B lymphocyte that created it—and no copy of the gene exists in the human germline. The only place to find a unique antibody gene is in the individual cells that created it.

The extraordinary process of gene rearrangement and mutation results in a multitude of unique B lymphocytes and consequently an incredibly diverse repertoire of antibodies in any given individual.

Elucidating the mechanisms behind the production of unique antibody genes must be considered one of the major achievements of medical research in the 20th century. Yet unfolding this mystery created another problem to solve: If antibodies were not produced from genes encoded in the human genome and the products of these genes were new to the body, why were these antibody molecules not recognized by the immune system as foreign substances—like any other foreign substance that they were intended to eradicate? How could the body distinguish the apparently "foreign" antibody molecules from the bona fide infectious intruders?

Unraveling the genetics of antibody production led to another major advance in medicine: the discovery of how an endless array of antibody proteins could be made in a way that individual molecules were always tolerated by the body.

In the early 1990s, research began to demonstrate that the production of antibodies was not an unregulated process. Rather, it was learned that the antibodies produced by each and every B lymphocyte were subject to intense scrutiny. Studies showed that B lymphocytes which produced acceptable antibodies were stimulated to grow while those that produced "autoreactive" antibodies were not. B lymphocytes that produced "good" antibodies were stimulated to proliferate and enabled to produce copious amounts of antibody in the event it was needed to ward off a harmful agent. B lymphocytes that rearranged genes to produce antibodies that were ineffective or were autoreactive were given signals that instructed them to engage in a process of programmed cell death. Thus, B lymphocytes producing harmful or useless antibodies are simply killed off. This mechanism for creating antibody diversity on the one hand, while protecting the individual from a mass of unwanted or intolerable antibody molecules on the other, was as elegant as it was fundamental to the success of vertebrate immune physiology.

This process of "selection" has been elucidated in great detail. There can be no more important feature of immune physiology than the process of selection. Selection is a fundamental step to enable the body to produce an extremely diverse set of antibody molecules without, in the process, producing an array of novel molecules that cause harm.

Industry Context

Until now each and every therapeutic antibody on the market has been derived from animals and/or through gene sequence modification in the laboratory to produce a desired antibody reactivity. Marketed antibodies to date, described as "fully human", are not derived from human gene sequences that have undergone the crucial process of selection in a human.

Without exception, all marketed products to date that are described as "fully human", are in fact engineered and are not selected based on natural tolerance in the human body. The use of the term "fully human" to describe these products has thus created considerable confusion. To our knowledge, there are at present no True HumanTM antibodies manufactured, using recombinant protein technology, currently marketed.

Platform Technology

Our True HumanTM antibody therapeutics are developed in-house using our proprietary discovery platform. There are significant technical challenges in identifying and cloning genes for True HumanTM antibodies. A key problem to overcome can be to first identify individuals with the desired antibody reactivity. This can involve screening thousands of blood donors to enable the identification of a single, clinically relevant antibody—discovered from literally trillions of irrelevant background antibody molecules in the blood of donors. To distinguish the clinically relevant antibodies from irrelevant background antibody molecules in donor bloods, we use our Super High Stringency Antibody Mining (SHSAMTM) technology. White blood cells from that individual can then be isolated, and the unique gene that produced the native antibody obtained. We currently obtain blood donor samples through a Research and Collaboration Agreement with the South Texas Blood & Tissue Center, a Texas 501(c)(3) non-profit corporation.

Novel cloning technologies developed at XBiotech have enabled us to clone the crucial antibody gene sequences from these donors in order to reproduce a True HumanTM antibody for use in clinical therapy. A True HumanTM monoclonal antibody should therefore not be confused with other marketed therapeutic monoclonal antibodies, such as those currently referred to as "fully human" antibodies.

Market Opportunity

We have a number of indications in various stages of clinical or pre-clinical development with significant market opportunities. These include an array of inflammatory conditions as well as infectious disease indications. The potential market opportunities in these various indications are vast and we believe our research and manufacturing technologies, designed to more rapidly, cost-effectively and flexibly produce new therapies, will be advantageous in each market space.

Our Strategy

Our objective is to fundamentally change the way drugs are developed and commercialized and become a leading biopharmaceutical company focused on the discovery, development and commercialization of therapeutic True HumanTM antibodies.

Product Pipeline

Our product development status for the end of the year 2022 was as follows:



Employees and Human Capital

Our management team is comprised of highly experienced pharmaceutical and biotechnology executives with successful track records in researching, developing, gaining approval for and commercializing novel medicines to treat serious diseases. Together, the management team has covered the spectrum of pharmaceutical antibody and drug discovery, preclinical research, formulation development, manufacturing, human clinical trials, regulatory submissions and approval, and global commercialization. Additionally, the team has significant experience in company formation, capital raises, mergers/acquisitions, business development, and sales and marketing in the biopharmaceutical industry. Our board of directors ("Board") is constituted by individuals with significant experience in the pharmaceutical and biotechnology industries. As of December 31, 2022, we had 85 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.

In response to the COVID-19 pandemic, commencing in March 2020, we implemented a work-from-home mandate and ceased all non-essential business travel. In the recent months, some employees have recommenced limited business travel and some have transitioned back to working on-site in conjunction with the implementation of additional safety and infection prevention measures including enhanced cleaning, additional personal protective equipment, and contact tracing protocols. We continue to provide our employees with the option to work from home.

Competition

The therapeutic antibody space is dynamic as there continues to be a highly active commercial pipeline of therapeutic antibodies globally, involving a complex array of development cycles as products reach the end of their patent life and as new candidate products proceed into pivotal studies and approach registration. There are numerous independent reviews on the subject in both trade journals and academic press (one such example being Reichert JM, Antibodies to watch in 2018 MAbs. 2018 Jan 4:1-21).

We believe True Human™ therapeutic antibodies have important differentiating factors from other monoclonal antibodies currently marketed. However, regardless of the potential advantages or uniqueness of our current or future product candidates in the market, we do expect these products to compete head-to-head with the numerous existing candidate antibody products in development, including emerging biosimilar therapeutic antibodies.

Safety

The Company's True Human $^{\text{TM}}$ antibodies are derived from a natural human immune response. It is expected that this will facilitate better tolerability when used as a therapeutic compared to humanized or "fully human" monoclonal antibodies. Antibody therapies are known to be associated with significant risk for infusion reactions, including serious anaphylactic reactions. It is the Company's belief that these reactions are, in large part, the result of using antibodies that were not derived from natural human immunity but rather had engineered specificities.

Intellectual Property

XBiotech has developed a large international intellectual property (IP) portfolio to protect important aspects of its technology, services, and products, including patents, trademarks and trade secrets.

Governmental Regulations

We operate in an industry that is regulated by various governmental agencies both in the U.S. and globally. The success of our business is heavily dependent on our products gaining regulatory approval. The compliance with regulations by the FDA in the U.S., the European Medicines Agency, or EMA in the European Union and other regulatory bodies in other geographic areas has a material effect on our capital expenditures, our earnings and competitive positions.

Our ability to finance our operations and commercialize our products (both in the U.S. and abroad) are tied to our ability to obtain regulatory approval for our products. In the U.S., 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. The regulatory approval process is unpredictable, costly and time-consuming with no guaranteed positive outcomes. Even if we believe clinical trials to be successful, the FDA or comparable foreign regulatory authority may deem our clinical trials insufficient and not providing adequate data on safety and adequacy. The FDA or comparable foreign regulatory approvals, if and when obtained, may contain substantial limitations on the use of the product, which would restrict our ability to sell the products to the public at large.

In the European Union and many other jurisdictions, in order to market and sell our products, we must obtain separate marketing approvals, such as from the EMA, and comply with numerous and varying regulatory requirements. 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 the future will ever obtain regulatory approval. Change in political leadership within the U.S. and elsewhere could result in shifts in regulatory policies as they pertain to our business. While we may be able to anticipate certain changes, policy statements often are not always translated into actionable legislation. Therefore, future regulatory changes may have a material impact on the timing and process of obtaining the regulatory approval for our product candidates.

Environmental Regulations

Our business is subject to numerous environmental, health and safety laws and regulations both in the U.S. and elsewhere, which include regulations relating to 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 waste.

We cannot eliminate the risk of contamination or injury from these materials, which would result in us being liable for resulting damages, including significant costs associated with civil or criminal fines or penalties.

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.
- Potential milestone payments, negotiated as a part of the sale of Bermikimab, are at the discretion of the buyer and may never materialize.

- 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, 2022.

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 fail 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, 2022, we recognized approximately \$31.5 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, which consumed \$420 million of our cash resources. 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.

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

The sustained COVID-19 global pandemic has disrupted our business operations, and we expect it to continue throughout the remainder of 2023 and possibly beyond. Depending upon the length and severity of the pandemic, which cannot be predicted, we may continue to experience disruptions that could materially and adversely impact our business including:

- If any third parties in our supply chain are or continue to be adversely impacted by restrictions resulting from the COVID-19 pandemic, including
 staffing shortages, production slowdowns, or disruptions in freight and other transportation services and delivery distribution systems, our supply chain
 may be disrupted, which would limit our ability to manufacture our product candidates for our clinical trials, to meet our obligations to manufacture
 drugs for Janssen under our clinical manufacturing agreement, or to conduct our research, development and clinical operations.
- The pandemic has already affected and may continue to affect our obligations and performance under our agreements with Janssen. We cannot predict
 the likely potential adverse impact of COVID-19 on Janssen's future purchase orders or our ability to complete the manufacturing required by those
 purchase orders.
- Various aspects of our clinical trials could be limited or take longer than expected, including delays or difficulties in enrolling patients in our clinical trials, in clinical trial site initiation, and in recruiting clinical site investigators and clinical site staff; increased rates of patients withdrawing from clinical trials; diversion of healthcare resources away from the conduct of clinical trials; interruption of key clinical trial activities such as clinical trials site data monitoring due to limitations on travel imposed or recommended by governmental authorities; impact on employees and others or interruption of clinical trial visits or study procedures which may impact the integrity of subject data and clinical study endpoints; and interruption or delays in the operations of the FDA and comparable foreign regulatory agencies, which may impact regulatory review and approval timelines.
- The FDA and comparable foreign regulatory agencies may experience disruptions, have slower response times or be under-resourced to continue to
 monitor our clinical trials or to conduct required activities and review of our product candidates seeking regulatory review, or may prioritize review and
 approval of COVID-19 treatments and vaccines over other product candidates, and such disruptions could materially affect the development, timing and
 approval of our product candidates.

The ultimate impact of the pandemic on us will depend on future developments, which cannot be accurately predicted. Given the uncertainties, we may be unable to maintain operations as planned prior to the COVID-19 pandemic.

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

To date, we have not generated any revenues 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. In addition, travel restrictions, shutdowns of or occupancy limitations on certain businesses, bans or restrictions on large public gatherings and declarations of states of emergency remain in effect in some cities, states and countries around the world in response to the ongoing COVID-19 pandemic. Spikes in the numbers of infected patients, the rise and spread of new COVID-19 variants, delays in vaccine distribution or administration, adverse reactions to existing or future COVID-19 vaccines or future similar regional or global health concerns could negatively affect our ability to recruit and retain subjects in clinical trials if they disproportionately impact the sites in which we conduct any of our trials, which would have a material adverse effect on our business and our results of operation and financial condition.

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 only at limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approva

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.

In the last couple of years, XBiotech has positioned itself with a pipeline of potential drug candidates at all stages of development, from pre-clinical through Phase III clinical trial stage. Even though we have many 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 app

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, 2022, we had 85 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, COVID-19 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

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 issue. 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, 2023 our directors, executive officers and principal shareholders, together with their affiliates, beneficially own, in the aggregate, at least 11.8 million shares or approximately 38.8% of our outstanding common stock, and could own approximately 14.2 million shares or approximately 43.3% 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 HumanTM 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.

Although XBiotech does not meet the definition of "Investment Company", for US federal income taxation purposes, we will be a passive foreign investment company (PFIC) if in any taxable year either: (a) 75% or more of our gross income consists of passive income; or (b) 50% or more of the value of our assets is attributable to assets that produce, or are held for the production of, passive income. If we meet either test, our 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. In previous taxable years, we likely were a PFIC because our gross income consisted principally of interest. In 2019, however, the character of our gross income changed significantly as a result of the Janssen Agreements, and the determination of whether we were a PFIC in 2022 is uncertain. Moreover, the 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 extremely 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 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, 2023, we had 30,439,275 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.

1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 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 product 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.

ITEM 3. LEGAL PROCEEDINGS

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

ITEM MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF 5. 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 10 record holders of our common stock as of February 22, 2023.

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 RESERVED

6. RESERVED

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

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, 2022 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 earnings as of December 31, 2022 were (\$27.7) million. We had a net loss of \$32.9 million for the year ended December 31, 2022, compared to a net loss of \$17.4 million for the year ended December 31, 2021. During the fiscal year of 2023, 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, 2022, we had 85 employees.

Components of Results of Operations

Revenues

Prior to receiving payments under the clinical manufacturing agreement entered into in connection with the sale of bermikimab, 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.

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.

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, 2022, we have recorded total research and development expenses, including share-based compensation, of \$279.1 million. Our total research and development expenses for the year ended December 31, 2022 was \$31.5 million, compared to \$28.3 million the year ended December 31, 2021. Share-based compensation accounted for \$3.6 million for the year ended December 31, 2022 and \$2.0 million for the year ended December 31, 2021.

Research and development expenses as a percentage of total operating expenses was 83% for the year ended December 31, 2022, and 75% for the year ended December 31, 2021. The percentages, excluding share-based compensation, were 85% for the year ended December 31, 2022, and 79% for the year ended December 31, 2021.

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

General and Administrative Expenses

General and administrative expense consists primarily of salaries and related expenses for personnel in administrative, finance, business development and human resource functions, as well as the legal costs of pursuing patent protection of our intellectual property and patent filing and maintenance expenses, share–based compensation, and professional fees for legal services. Our total general and administration expenses was \$6.3 million for the year ended December 31, 2022, and \$9.4 million for the year ended December 31. Share-based compensation accounted for \$1.4 million for the year ended December 31, 2022, and \$2.2 million for the year ended December 31, 2021.

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, | | | | | |
|--|----------------------------|-----------|--|--|--|--|
| | 2022 | 2021 | | | | |
| Weighted-average grant date fair value per share | \$ 4.92 \$ | 9.29 | | | | |
| Expected volatility | 82%-83% | 83%-91% | | | | |
| Risk-free interest rate | 1.5%-4.1% | 0.5%-1.4% | | | | |
| 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, with the exception of certain Canada deferred tax assets that will reverse in a period in which they may be carried back, we have provided a valuation allowance against our deferred tax assets as we believe the objective and verifiable evidence of our historical pretax net losses outweighs any positive evidence of our forecasted future results. Although we believe that our tax estimates are reasonable, the ultimate tax determination involves significant judgment. We will continue to monitor the positive and negative evidence and will adjust the valuation allowance as sufficient objective positive evidence becomes available.

We account for uncertain tax positions by recognizing the financial statement effects of a tax position only when, based upon technical merits, it is more likely than not that the position will be sustained upon examination. We recognize 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 year ended December 31, 2022, and 2021 are summarized as follows (in thousands):

| | Year Ended December 31, | | | | | |
|------------------------|-------------------------|----|--------|--|--|--|
| | 2022 | | 2021 | | | |
| Revenue | | | | | | |
| Manufacturing revenue | \$ 4,010 | \$ | 18,000 | | | |
| Clinical Trial revenue | - | | 394 | | | |
| Total revenue | \$ 4,010 | \$ | 18,394 | | | |

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.

Under the clinical manufacturing agreement with Janssen, we have recorded \$18.0 million as manufacturing revenue for the year ended December 31, 2021. Clinical trial revenue for the year ended December 31, 2021 includes \$303 thousand pass-through revenue for two ongoing trials and \$91 thousand mark-up revenue.

Cost of Goods Sold

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

| | Ye | Year Ended December 31, | | | | | |
|--------------------------|----|-------------------------|------|-------|--|--|--|
| | 20 | 22 | 2021 | | | | |
| Cost of goods sold | | | | | | | |
| Manufacturing cost | \$ | 651 | \$ | 5,517 | | | |
| Clinical trial cost | | <u>-</u> | | 303 | | | |
| Total cost of goods sold | \$ | 651 | \$ | 5,820 | | | |

We had not incurred any cost of goods sold before the year 2020. The manufacturing cost represents period expense for manufacturing, quality assurance and quality control departments. Drug for the Janssen Transaction was mainly manufactured in the year 2020. Part of the cost was deferred to the year 2021. Clinical trial cost for the year ended December 31, 2021, is \$303 thousand, which is the pass-through expenses for two trials. These two trials were completed in December 2020.

Expenses

Research and Development

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

| | Year Ended | | | | | | | | |
|--|--------------|--------|------|--------|-----------|----------|------------|-----------|------------|
| | December 31, | | | |] | Increase | % Increase | | |
| | 2022 2021 | | 2021 | | 2022 2021 | | (1 | Decrease) | (Decrease) |
| Salaries and related expenses | \$ | 10,534 | \$ | 12,235 | \$ | (1,701) | -14% | | |
| Laboratory and manufacturing supplies | | 6,477 | | 4,749 | | 1,728 | 36% | | |
| Clinical trials and sponsored research | | 2,047 | | 1,390 | | 657 | 47% | | |
| Share-based compensation | | 3,641 | | 2,020 | | 1,621 | 80% | | |
| Other | | 8,845 | | 7,874 | | 971 | 12% | | |
| Total | \$ | 31,544 | \$ | 28,268 | \$ | 3,276 | 12% | | |

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 12% to \$31.5 million for year ended December 31, 2022 compared to \$28.3 million for the year ended December 31, 2021. The increase was mainly due to the shift in operating activities as a result of the termination of the clinical trial manufacturing agreement in the Janssen Transaction. The increase of share-based compensation is due to the new grants to employees in the fourth quarter of 2021. Salaries and related expenses decreased because of the year-end bonus to employees only in 2021.

General and Administrative

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

| | Year Ended December 31, Increase | | | | | | | |
|-------------------------------|-------------------------------------|-------|---|-------|----|------------|------------|--|
| | 2022 | | , in the second | | | (Decrease) | (Decrease) | |
| Salaries and related expenses | \$ | 2,494 | \$ | 3,971 | \$ | (1,477) | -37% | |
| Patent filing expense | | 540 | | 794 | | (254) | -32% | |
| Share-based compensation | | 1,421 | | 2,162 | | (741) | -34% | |
| Professional fees | | 1,035 | | 1,469 | | (434) | -30% | |
| Other | | 815 | | 992 | | (177) | -18% | |
| Total | \$ | 6,305 | \$ | 9,388 | \$ | (3,083) | -33% | |

General and administrative expenses decreased 33% to \$6.3 million for the year ended December 31, 2022 compared to \$9.4 million for the year ended December 31, 2021. The salaries and related expenses decreased \$1.5 million mainly due to a \$3.8 million bonus to the Chief Executive Officer in June 2022 compared to a \$7.0 million bonus in June 2021, 40% of which was allocated to general and administrative expenses for both periods. The share-based compensation decrease was mainly due to the fully amortized grants to employees in the previous year. In addition, professional fees decreased \$0.4 million mainly due to the decrease in audit and tax service fees in 2022.

Other Income

The following table summarizes other income (in thousands):

| | Year Ended December 31, | | | | | |
|------------------------------|-------------------------|----------|--|--|--|--|
| | 2022 | 2021 | | | | |
| Interest income | \$ 3,823 | \$ 467 | | | | |
| Other expense | (121) | (132) | | | | |
| Foreign exchange gain (loss) | (2,800) | (711) | | | | |
| Total | \$ 902 | \$ (376) | | | | |

The interest income for the year ended December 31, 2022 and 2021 was mainly due to the interest generated from the Company's Canadian bank accounts and time deposits. Foreign exchange loss was mainly due to the fluctuation between the US dollar and the Canadian dollar in the year ended December 31, 2022 compared to 2021.

Income Taxes

The Company's income tax benefit for the tax years end December 31, 2022 and 2021 of \$0.7 million, and \$8.0 million, were primarily driven by estimated Canadian loss carrybacks to 2019 of \$0.6 million and \$9.5 million, respectively.

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, 2022, we have funded our operations principally through private placements and public offerings of equity securities, which have provided aggregate cash proceeds of approximately \$118.2 million. We received \$675 million in cash proceeds from the Janssen Transaction in the year ended December 31, 2019. In June 2021, we received the remaining \$75 million in cash from the escrow receivable from the same transaction. In July 2021, we paid \$75 million in dividends to shareholders. In July 2022, we purchased interest bearing time deposits in the amount of \$63.3 million for a one year term. At December 31, 2022, we had cash and cash equivalents of \$157.3 million as compared to cash and cash equivalents of \$237.0 million at December 31, 2021. The following table summarizes our sources and uses of cash (in thousands):

| | Year Ended Dec | | | | | | |
|--|----------------|----|----------|--|--|--|--|
| Net cash (used in) provided by: | 2022 | | 2021 | | | | |
| Operating activities | \$ (14,824) | \$ | 69,445 | | | | |
| Investing activities | (63,892) | | (3,525) | | | | |
| Financing activities | - | | (67,008) | | | | |
| Effect of foreign exchange rate on cash and cash equivalents | (961) | | 705 | | | | |
| Net change in cash and cash equivalents | \$ (79,677) | \$ | (383) | | | | |

Operating Activities

During the years ended December 31, 2022 and 2021 net cash (used in) provided by operating activities was \$(14.8) million and \$69.4 million, respectively. Net cash used in the year ended December 31, 2022 primarily resulted from our net income and losses, whereas for the year ending December 31, 2021 the company received \$75 million from escrowed funds from the sale of bermekimab.

Investing Activities

During the years ended December 31, 2022 and 2021, our investing activities used net cash of \$63.9 million, and \$3.5 million, respectively. The change in the year 2022 was mainly caused by the interest bearing time deposits we purchased in July 2022, in the amount of \$63.3 million, the maturity term of which is one year. The use of cash in the year 2021 was for building expansion and the warehouse in construction.

Financing Activities

During the years ended December 31, 2022 and 2021, our financing activities used net cash proceeds of \$0 and \$67 million, respectively. In July 2021, we paid \$75 million in dividends to shareholders. During the year ended December 31, 2021, employee exercised stock options to purchase a total of 1.1 million shares of our common stock for approximately \$8.0 million in net proceeds.

We expect to continue to incur operating losses in the future. The clinical manufacturing agreement with Janssen terminated in November 2022, after which we do not expect to receive any additional revenue under that agreement other than the potential milestone payment. As of December 31, 2022, our principal sources of liquidity were our cash and cash equivalents, which totaled approximately \$157.3 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.

$rac{ ext{ITEM}}{8.}$ FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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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 sheet of XBiotech Inc. and subsidiaries (the "Company") as of December 31, 2022, and the related consolidated statements of operations, comprehensive loss, shareholders' equity, and cash flows for the year then ended, and the related notes (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, 2022, and the results of their operations and their cash flows for the year 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 audit. 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit 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 audit 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 audit 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 audit 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 audit provides 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, 2023

Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of XBiotech Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of XBiotech Inc. (the Company) as of December 31, 2021 and 2020, the related consolidated statements of operations, comprehensive income (loss), shareholders' equity and cash flows for each of the three years in the period ended December 31, 2021, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2021 and 2020, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2021, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's 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 audit 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 Company'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 Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgements. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Accrued Clinical Trial Cost

Description of the Matter

As discussed in Note 2 to the consolidated financial statements, the Company records accruals for clinical trial activities based upon estimates of costs incurred through the balance sheet date that have yet to be invoiced by the clinical trial sites and third-party service providers. The Company's accrual for clinical trial costs totaled \$618 thousand at December 31, 2021.

Auditing the Company's accruals for clinical trials is challenging due to the fact that information necessary to estimate the accrual includes significant assumptions derived from patient visits and project duration, and such assumptions are accumulated from multiple sources. Specifically, in certain circumstances, the determination of the nature and level of services received during the reporting period requires judgement because the timing and pattern of the vendor invoicing may not correspond to the timing and level of services provided and there may be a delay in invoicing from clinical trial sites and third party service providers.

How we Addressed the Matter in Our Audit To evaluate the accrual for clinical trial cost, our audit procedures included, among others, testing the completeness and accuracy of the underlying data used in the estimates and evaluating the significant assumptions including, but not limited to, patient visits and project duration, that are used by management to estimate the recorded accruals. To assess the reasonableness of the significant assumptions, we corroborated the progress of clinical trials with the Company's clinical trial management team by performing inquiries of management, obtaining evidence directly from active patient sites, and verifying the active patient sites and currently enrolled patients to contracts or other third party documentation. We performed a look back analysis to identify and evaluate material inconsistencies within the historically recorded accruals and actual amounts realized through the current period. We also obtained subsequent invoices received from such third parties and any pending change orders to assess the impact to the recorded accruals through our report date and compared that to the accrued clinical trial cost as of the balance sheet date.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2005.

Austin, Texas

March 15, 2022

Consolidated Balance Sheets (in thousands, except share data)

| Assets Current assets: Cash and cash equivalents Interest bearing time deposit Accrued interest receivable Income tax receivable Prepaid expenses and other current assets Total current assets Property and equipment, net Total assets Liabilities and shareholders' equity Current liabilities: | 60,172 1,216 548 601 219,843 26,260 3 246,103 | \$ | 236,983 - 8,953 934 246,870 28,307 275,177 |
|---|---|----|--|
| Current assets: Cash and cash equivalents Interest bearing time deposit Accrued interest receivable Income tax receivable Prepaid expenses and other current assets Total current assets Property and equipment, net Total assets Liabilities and shareholders' equity | 60,172 1,216 548 601 219,843 26,260 3 246,103 | | 8,953 934 246,870 28,307 |
| Cash and cash equivalents Interest bearing time deposit Accrued interest receivable Income tax receivable Prepaid expenses and other current assets Total current assets Property and equipment, net Total assets Liabilities and shareholders' equity | 60,172 1,216 548 601 219,843 26,260 3 246,103 | | 8,953 934 246,870 28,307 |
| Interest bearing time deposit Accrued interest receivable Income tax receivable Prepaid expenses and other current assets Total current assets Property and equipment, net Total assets Liabilities and shareholders' equity | 60,172 1,216 548 601 219,843 26,260 5 246,103 | | 8,953 934 246,870 28,307 |
| Accrued interest receivable Income tax receivable Prepaid expenses and other current assets Total current assets Property and equipment, net Total assets Liabilities and shareholders' equity | 1,216 548 601 219,843 26,260 246,103 | \$ | 934 246,870 28,307 |
| Income tax receivable Prepaid expenses and other current assets Total current assets Property and equipment, net Total assets Liabilities and shareholders' equity | 548 601 219,843 26,260 5 246,103 | \$ | 934 246,870 28,307 |
| Prepaid expenses and other current assets Total current assets Property and equipment, net Total assets Liabilities and shareholders' equity | 601 219,843 26,260 246,103 | \$ | 934 246,870 28,307 |
| Total current assets Property and equipment, net Total assets Liabilities and shareholders' equity | 219,843 26,260 246,103 | \$ | 246,870 28,307 |
| Property and equipment, net Total assets Liabilities and shareholders' equity | 26,260 246,103 | \$ | 28,307 |
| Total assets Liabilities and shareholders' equity | 246,103 | \$ | |
| Liabilities and shareholders' equity | | \$ | 275,177 |
| • • | | | |
| • • | | | |
| Current Habitutes: | | | |
| Accounts payable \$ | 2,408 | \$ | 2,069 |
| Accrued expenses | 1,603 | _ | 1,374 |
| Income tax payable | 55 | | 10 |
| Total current liabilities | 4,066 | | 3,453 |
| Long-term liabilities: | ,,,,, | | -, |
| Income tax payable | 1,576 | | 1,466 |
| Deferred tax liability | 59 | | 873 |
| Total liabilities | 5,701 | | 5,792 |
| Shareholders' equity: | | | |
| Preferred stock, no par value, unlimited shares authorized, no shares outstanding | _ | | _ |
| Common stock, no par value, unlimited shares authorized, both 30,439,275 shares issued and outstanding at | | | |
| December 31, 2022 and December 31, 2021 | 267,325 | | 262,263 |
| Accumulated other comprehensive income | 826 | | 1,971 |
| (Accumulated deficit) retained earnings | (27,749) | | 5,151 |
| Total shareholders' equity | 240,402 | | 269,385 |
| Total liabilities and shareholders' equity \$ | 246,103 | \$ | 275,177 |

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

| | Year Ended De 2022 | | | ber 31, 2021 |
|---|-----------------------|------------|----|-----------------|
| Revenue: | | | | |
| Manufacturing revenue | \$ | 4,010 | \$ | 18,000 |
| Clinical trial service revenue | | - | | 394 |
| Total revenue | | 4,010 | | 18,394 |
| Cost of goods sold: | | | | |
| Manufacturing cost | | 651 | | 5,517 |
| Clinical trial cost | | - | | 303 |
| Total cost of goods sold | | 651 | | 5,820 |
| Gross margin | | 3,359 | | 12,574 |
| | | | | |
| Operating expenses: | | | | |
| Research and development | | 31,544 | | 28,268 |
| General and administrative | | 6,305 | | 9,388 |
| Total operating expenses | | 37,849 | | 37,656 |
| Loss from operations | | (34,490) | | (25,082) |
| | | | | |
| Other income (loss): | | | | |
| Interest income | | 3,823 | | 467 |
| Other expense | | (121) | | (132) |
| Foreign exchange loss | | (2,800) | | (711) |
| Total other income (loss) | | 902 | | (376) |
| Income before income taxes | | (33,588) | | (25,458) |
| Benefit for income taxes | _ | 688 | | 8,044 |
| Net loss | \$ | (32,900) | \$ | (17,414) |
| Net loss per share—basic | \$ | (1.08) | \$ | (0.58) |
| Shares used to compute basic net loss per share | | 30,439,275 | | 30,043,380 |
| Net loss per share—diluted | \$ | (1.08) | \$ | (0.58) |
| Shares used to compute diluted net loss per share | | 30,439,275 | | 30,043,380 |

See accompanying notes to consolidated financial statements.

Consolidated Statements of Comprehensive Loss (in thousands)

| | Year Ended December 31, | | | | |
|---|-------------------------|----------|------|----------|--|
| | | 2022 | 2021 | | |
| | | | | | |
| Net loss | \$ | (32,900) | \$ | (17,414) | |
| Reclassification adjustment for foreign currency translation adjustment | | (1,567) | | - | |
| Foreign currency translation adjustment | | 422 | | 705 | |
| Comprehensive loss | \$ | (34,045) | \$ | (16,709) | |

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 (Loss) | Retained Earnings (Accumulated deficit) | Total |
|--|---------------------|---------------------------|--|--|---------------|
| Balance at December 31, 2020 | 29,304 | \$ 249,805 | \$ 1,266 | \$ 97,568 | \$ 348,639 |
| Net loss | - | - | - | (17,414) | (17,414) |
| Foreign currency translation adjustment | - | - | 705 | - | 705 |
| Issuance of common stock under stock option plan | 1,135 | 7,995 | - | - | 7,995 |
| Dividends | - | - | - | (75,003) | (75,003) |
| Share-based compensation expense | - | 4,463 | - | - | 4,463 |
| 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 |

 $See\ accompanying\ notes\ to\ consolidated\ financial\ statements.$

Consolidated Statements of Cash Flows (in thousands)

| | Year Ended December 31, 2022 2021 | | |
|---|-----------------------------------|-------------|------------|
| Operating activities | | | |
| Net loss | \$ | (32,900) \$ | (17,414) |
| Adjustments to reconcile net loss to net cash (used in) provided by operating activities: | • | (==,===) + | (=:, := :) |
| Depreciation | | 2,614 | 2,648 |
| Foreign exchange loss | | 2,800 | - |
| Share-based compensation expense | | 5,062 | 4,463 |
| Changes in operating assets and liabilities: | | | |
| Account receivable | | - | 4,113 |
| Income tax receivable | | 8,556 | (2,380) |
| Deferred cost of goods sold | | - | 2,177 |
| Accrued interest receivable | | (1,216) | - |
| Escrow receivable | | - | 75,063 |
| Prepaid expenses and other current assets | | 334 | (352) |
| Deferred tax asset | | - | 533 |
| Accounts payable | | 357 | (514) |
| Accrued expenses | | 229 | 23 |
| Income tax payable | | 155 | 212 |
| Deferred tax liability | | (815) | 873 |
| Net cash (used in) provided by operating activities | | (14,824) | 69,445 |
| Investing activities | | | |
| Purchase of property and equipment | | (585) | (3,525) |
| Purchase of interest bearing time deposit | | (63,307) | - |
| Net cash used in investing activities | | (63,892) | (3,525) |
| | | | |
| Financing activities | | | |
| Dividends | | - | (75,003) |
| Issuance of common stock under stock option plan | | <u> </u> | 7,995 |
| Net cash used in financing activities | | - | (67,008) |
| Effect of foreign exchange rate on cash and cash equivalents | | (961) | 705 |
| Net change in cash and cash equivalents | | (79,677) | (383) |
| Cash and cash equivalents, beginning of period | | 236,983 | 237,366 |
| | \$ | 157,306 \$ | 236,983 |
| Cash and cash equivalents, end of period | Ψ | 157,500 | 230,303 |
| Supplemental Information: | | | |
| Purchases of property and equipment in accounts payable | | 18 | 93 |
| See accompanying note to consolidated financial statements. | | | |

Notes to Consolidated Financial Statements

1. Organization

XBiotech Inc. (XBiotech or the Company) was incorporated in Canada on March 22, 2005. XBiotech USA, Inc., a wholly-owned subsidiary of the Company, was incorporated in Delaware, United States in November 2007. XBiotech Germany GmbH, a wholly-owned subsidiary of the Company, was incorporated in Germany in January 2014. The Company's headquarters are located in Austin, Texas.

Since its inception, XBiotech has focused on advancing technology to rapidly identify and clone antibodies from individuals that have resistance to disease. At the heart of the Company is a proprietary technical knowhow to translate natural human immunity into therapeutic product candidates. The Company has in its pipeline both anti-infective and anti-inflammatory candidate therapeutics derived from this technology.

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

The Company continues to be subject to a number of risks common to companies in similar stages of development. Principal among these risks are the uncertainties of technological innovations, dependence on key individuals, development of the same or similar technological innovations by the Company's competitors and protection of proprietary technology. The Company's ability to fund its planned clinical operations, including completion of its planned trials, is expected to depend on the amount and timing of cash receipts from future collaboration or product sales and/or financing transactions. The Company believes that its cash and cash equivalents of \$157.3 million at December 31, 2022, will enable the Company to achieve several major inflection points, including potential new clinical studies with lead product candidates. The Company expects to have sufficient cash through 12 months from the date of this report.

2. Significant Accounting Policies

Basis of Presentation

These consolidated financial statements have been prepared in conformity with 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, 2022 and 2021, the results of its operations and comprehensive loss for the years ended December 31, 2022, and 2021, and the cash flows for the years ended December 31, 2022, and 2021.

Basis of Consolidation

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

Use of Estimates

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

Revenue

Revenue from Janssen Agreements

The Company recognizes revenues from its Janssen Agreements as follows.

The Company entered into its clinical manufacturing and clinical trial services arrangements in connection with its sale of certain intellectual property on December 30, 2019. These contracts commenced January 1, 2020. The Company executed 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 is applying the revenue recognition guidance by analogy.

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

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

Manufacturing Revenue

The Company had a Clinical Manufacturing Agreement that it accounts for by analogy to ASC 606, under which it agreed to manufacture bermekimab for use by Janssen in clinical trials, in exchange for payments of \$4.5 million per quarter, for the year ended 2020 and 2021. In 2022 the Company executed a new manufacturing agreement with a Janssen related company. The agreement generated \$4.0 million in revenue through November 2022.

Clinical Trial Service Revenue

On December 30, 2019, the Company entered into a Transition Services Agreement with Janssen. Pursuant to the Transition Services Agreement, the Company agreed to continue operational management, on a fee-for-service basis, of two clinical trials related to bermekimab.

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

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

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

The Company recognizes and measure uncertain tax benefits in accordance with ASC 740 Income Taxes ("ASC 740") based on a two-step process in which (1) the Company determines whether it is more likely than not that the tax position will be sustained based on the technical merits of the position, and (2) for those tax positions that meet the more-likely-than-not recognition threshold, the Company recognizes the largest amount of tax benefit that is more than fifty percent likely to be realized upon ultimate settlement with the related tax authority. The Company's policy is to recognize interest and penalties related to uncertain tax positions, if any, in income tax expense.

Share-Based Compensation

The Company accounts for its share-based compensation awards in accordance with ASC Topic 718, *Compensation-Stock Compensation* ("ASC 718"), which 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, 2022, and 2021 was included in the following line items on the Consolidated Statements of Operations (in thousands).

| | Year Ended December 31, | | | |
|--|----------------------------|----|-------|--|
| | 2022 | | 2021 | |
| Research and development | \$ 3,641 | \$ | 2,019 | |
| General and administrative | 1,421 | | 2,162 | |
| Cost of goods sold | - | | 282 | |
| Total share-based compensation expense | \$ 5,062 | \$ | 4,463 | |

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, | | | | | |
|--|----------------------------|---------|------|------|---------|------|
| | | | | 2021 |)21 | |
| Weighted-average grant date fair value per share | 9 | \$ 4.92 | 2 | | \$ 9.29 | |
| Expected volatility | 82% | - | 83% | 83% | - | 91% |
| Risk-free interest rate | 1.5% | - | 4.1% | 0.5% | - | 1.4% |
| 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.

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, 2022 and 2021, the Company did not have any assets or liabilities that are measured at fair value on a recurring basis. The carrying amounts reflected in the balance sheets for cash and cash equivalents, interest bearing time deposit, prepaid expenses and other current assets, accounts payable, and accrued expenses approximate their fair values at December 31, 2022 and 2021, due to their short-term nature.

Property and Equipment

Property and equipment, which consists of land, construction in process, furniture and fixtures, computers and office equipment, scientific equipment, leasehold improvements, vehicles and building are stated at cost and depreciated 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. 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, 2022.

Foreign Currency Transactions

Certain transactions are denominated in a currency other than the Company's functional currency of the U.S. dollar, and the Company generates assets and liabilities that are fixed in terms of the amount of foreign currency that will be received or paid. At each balance sheet date, the Company adjusts the assets and liabilities to reflect the current exchange rate, resulting in a translation gain or loss. Transaction gains and losses are also realized upon a settlement of a foreign currency transaction in determining net loss for the period in which the transaction is settled.

Comprehensive Income (Loss)

ASC Topic 220, *Comprehensive Income*, requires that all components of comprehensive income (loss), including net income (loss), be reported in the financial statements in the period in which they are recognized. Comprehensive income (loss) is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources, including 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 FASB issued ASU No. 2016-13, Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments. This ASU requires instruments measured at amortized cost to be presented at the net amount expected to be collected. Entities are also required to record allowances for available-for-sale debt securities rather than reduce the carrying amount. On November 15, 2019, the FASB delayed the effective date of the standard for certain small public companies and other private companies. As amended, the effective date of ASC Topic 326 was delayed until fiscal years beginning after December 15, 2022 for SEC filers that are eligible to be smaller reporting companies under the SEC's definition, as well as private companies and not-for-profit entities. The Company expects that the adoption will not have a material impact on its consolidated financial statements.

3. Revenue

On December 30, 2019, the Company entered into a Transition Services Agreement with Janssen. Pursuant to the Transition Services Agreement, the Company has agreed to continue operational management, on a fee-for-service basis, of two ongoing clinical trials related to bermekimab. In consideration for all of the services to be provided, for each calendar quarter during the term of such agreement, Janssen shall pay the Company a fee for such quarter equal to all pass-through costs incurred by the Company during such calendar quarter, exclusive of the allocation of certain internal costs that are not considered pass-through pursuant to the agreement, plus a markup of 30%. 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 has recorded \$4.0 million of gross revenue under the February 2022 agreement.

For the year ended December 31, 2021, the Company has recorded \$18.0 million of manufacturing revenue and \$394 thousand of clinical trial service revenue.

4. Property and Equipment and Building Construction in Progress

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

| | 2022 | 2021 |
|-------------------------------|--------------|--------------|
| Computer and office equipment | \$ 274 | \$ 557 |
| Furniture and fixtures | 129 | 130 |
| Land | 1,418 | 1,418 |
| Scientific equipment | 16,059 | 16,829 |
| Vehicle | 112 | 82 |
| Building | 24,173 | 22,773 |
| Mobile facility | 189 | 189 |
| Construction in process | 401 | 2,061 |
| Accumulated depreciation | (16,495) | (15,732) |
| | \$ 26,260 | \$ 28,307 |

Depreciation expenses related to property and equipment amounted to both approximately \$2.6 million, for the years ended December 31, 2022, and 2021, respectively. Construction in process is related to research and development and manufactory equipment. Depreciation expense is recorded to cost of goods sold, 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, 2022, and 2021 (in thousands):

| | , | 2022 | 2021 |
|---|----|-------|-------------|
| Accrued compensation and related expenses | \$ | 489 | \$ 480 |
| Accrued professional fees | | 117 | 163 |
| Accrued clinical trial expenses | | 928 | 618 |
| Other | | 69 | 113 |
| | \$ | 1,603 | \$ 1,374 |

6. Common Stock

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

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

No stock options were exercised from January 1, 2022 through 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, 2020 | 5,327,425 | \$2.71 - \$21.99 | \$ 6.09 |
| Granted | 809,500 | 11.35 - 20.20 | 13.47 |
| Exercised | (1,348,374) | 3.27 - 15.00 | 7.78 |
| Forfeitures | (131,874) | 4.14 - 21.99 | 12.23 |
| 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 |

The weighted average fair value of the options issued to directors, employees and consultants during the fiscal years ended December 31, 2022, and 2021, was \$4.92 and \$9.29, respectively. 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, 2022, and 2021 was \$5.6 million, and \$4.8 million, respectively.

As of December 31, 2022, there was approximately \$2.8 million of unrecognized compensation cost, related to stock options granted under the Plan which will be amortized to stock compensation expense over the next 1.12 years. The weighted-average remaining contractual term of outstanding options as of December 31, 2022 is 5.75 years. Total exercisable stock options as of December 31, 2022 is 4.1 million. The weighted-average exercise price of options exercisable as of December 31, 2022 is \$10.32 per share and the weighted-average remaining contractual term is 5.42 years.

8. Net Income/Loss Per Share

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

| | Year Ended December 31, | | | |
|--|-------------------------|----|------------|--|
| | 2022 | | 2021 | |
| Net loss | \$ (32,900) | \$ | (17,414) | |
| Weighted-average number of common shares—basic | 30,439,275 | | 30,043,380 | |
| Net loss per share—basic | \$ (1.08) | \$ | (0.58) | |
| Weighted-average number of common shares—diluted | 30,439,275 | | 30,043,380 | |
| Net loss per share—diluted | \$ (1.08) | \$ | (0.58) | |

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 | d December 31, |
|---------------|------------|----------------|
| | 2022 | 2021 |
| Stock options | 4,558,902 | 2 4,656,677 |

9. Income Taxes

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

| | | Years Ended December 31, | | | |
|---------------|----|--------------------------|------|----------|--|
| | | 2022 | 2021 | | |
| United States | | \$ (28,161) | \$ | 5,301 | |
| Canada | | (4,973) | (| (30,127) | |
| Other Foreign | | (454) | | (632) | |
| Total | | \$ (33,588) | \$ (| (25,458) | |
| | | | | | |
| | 63 | | | | |

The components of the provision for income taxes are as follows for the years ended December 31, 2022, and 2021 (in thousands):

| Current | 2022 | 2021 |
|--------------------------|-------------|---------------|
| United States | \$ 457 | \$ 17 |
| Canada | (334) | (9,486) |
| Other Foreign | 5 | 14 |
| Total | \$ 128 | \$ (9,455) |
| Deferred | | |
| United States | - | - |
| Canada | (805) | 1,505 |
| Other Foreign | (11) | (94) |
| Total | (816) | 1,411 |
| | | |
| Total income tax expense | \$ (688) | \$ (8,044) |

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, 2022, and 2021:

| | 2022 | 2021 |
|---|---------|--------|
| T | 27.00/ | 27.00/ |
| Income tax benefit computed at federal tax rate | 27.0% | 27.0% |
| Foreign operations | (4.1)% | (0.9)% |
| Capital gains and foreign exchange | 0.0% | 0.0% |
| Change in valuation allowance | (14.6)% | 4.1% |
| Tax credits generated | 3.5% | 1.6% |
| Prior year adjustments | 0.4% | 0.9% |
| Changes in uncertain tax positions | (0.3)% | (1.5)% |
| Foreign exchange gain and loss | (1.6)% | 1.5% |
| Stock compensation | (2.3)% | 2.2% |
| Non-deductible compensation | (5.8)% | (3.0)% |
| Other | (0.2)% | (0.3)% |
| Total | 2.0% | 31.6% |

The effective tax rate for the period ended December 31, 2022 varied from the Canadian statutory rate primarily due to losses in jurisdictions for which a valuation allowance is recorded and no benefit is recognized, 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 effective tax rate for the period ended December 31, 2021 varied from the Canadian statutory rate primarily due to valuation allowance activity 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:

| | 2022 | 2021 |
|--|----------|---------|
| Net operating loss carryforwards | - | 112 |
| Research and other credits | 3,820 | 3,360 |
| Stock based compensation | 2,703 | 3,235 |
| Capitalized research expenses | 5,210 | - |
| Share issue costs | 229 | 425 |
| Accrued liabilities | 294 | 227 |
| Foreign exchange | 687 | 206 |
| Deferred tax assets before Valuation allowance | 12,944 | 7,565 |
| Valuation allowance | (11,225) | (6,474) |
| Deferred tax assets | 1,719 | 1,091 |
| | | |
| Depreciation | 710 | 824 |
| Prepaid assets | 93 | 69 |
| Uncollectible debts | 975 | 1,057 |
| Foreign exchange | | 14 |
| Deferred tax liability | 1,777 | 1,964 |
| Net deferred tax asset (liability) | (59) | (873) |

For the year ended December 31, 2022, the Company had no Canadian or USA net operating loss carryforwards. The Canadian taxable loss for the period ended December 31, 2022 of \$2.2 million will be carried back to offset prior year taxable income. The Company also has \$5.3M of 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. Also, after weighing all available and positive and negative evidence the Company determined a full valuation allowance for the USA, Canada, and other foreign activity was necessary, consistent with prior year.

For the year ended December 31, 2022, the Company has not recorded any outside basis difference deferred 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 2019, 2019, and 2018 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, 2022, and 2021 is as follows (in thousands):

| | 2022 | 2021 |
|--|-------|-------|
| Balance as of January 1 | 2,389 | 2,060 |
| Additions based on tax positions related to the current year | 130 | 42 |
| Additions for tax positions of prior years | 346 | 287 |
| Balance at December 31 | 2,864 | 2,389 |
| | | · |

The Company recognized interest and penalties related to unrecognized tax benefits of \$63 thousand, and \$56 thousand as a component of income tax expense for the years ended December 31, 2022, and 2021, respectively. As of December 31, 2022, and 2021, there are \$1.6 million, and \$1.5 million, respectively, of unrecognized tax benefits that if recognized would affect the annual effective tax rate. In addition, it is reasonably possible that approximately \$0.5 million 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 increase or decrease within 12 months.

10. Selected Quarterly Financial Data (Unaudited)

Selected Quarterly Financial Data (Unaudited) for the year ended December 31, 2022 and 2021 is presented below (in thousands except per share data):

| | | | Second | | | Fourth |
|--------------------------------------|----|---------------|----------------|-----|------------|---------------|
| 2022 | I | First Quarter | Quarter | Thi | rd Quarter | 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) |

| | | | Second | | | Fourth |
|--------------------------------------|----|--------------|----------------|-----|-------------|---------------|
| 2021 | F | irst Quarter | Quarter | Thi | ird Quarter | Quarter |
| Loss from operations | \$ | (3,553) | \$ (10,605) | \$ | (3,731) | \$ (7,193) |
| Net loss | | (2,568) | (5,118) | | (3,261) | (6,467) |
| Net loss per share—basic and diluted | | (0.09) | (0.17) | | (0.11) | (0.21) |

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, 2022, 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 fourth quarter of the year ended December 31, 2022 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Limitations on Effectiveness of Controls and Procedures

In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints, and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

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, 2023 with the Securities and Exchange Commission in connection with the solicitation of proxies for our 2023 Annual Meeting of Stockholders to be held on June 23, 2023.

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) |
| <u>3.1</u> | 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) |
| <u>4.1</u> | Description of Registrant's securities registered pursuant to Section 12 of the Securities Exchange Act of 1934 |
| <u>10.1+</u> | 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) |
| <u>10.2+</u> | 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) |
| <u>10.3</u> | 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) |
| <u>10.4+</u> | 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) |
| | 69 |

| <u>10.5+</u> | 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) |
|---------------|--|
| <u>10.6</u> | 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) |
| <u>10.8+</u> | 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) |
| <u>10.9+</u> | Form of Incentive Share Option Agreement under the 2015 Equity Incentive Plan |
| <u>10.10+</u> | Form of Nonqualified Share Option Agreement under the 2015 Equity Incentive Plan |
| <u>10.11+</u> | 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) |
| <u>10.12+</u> | 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. |
| 10.14+* | Board Member Agreement, dated as of March 20, 2018, by and between XBiotech Inc. and Donald H. MacAdam. |
| 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) |
| <u>10.16†</u> | 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) |
| <u>10.17†</u> | 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) |
| <u>10.18†</u> | <u>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)</u> |
| 21.1* | <u>List of subsidiaries</u> |
| | 70 |

- 23.1* Consent of Independent Registered Public Accounting Firm, Whitley Penn LLP
- 23.2* Consent of Independent Registered Public Accounting Firm, Ernst & Young 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
- The following financial statements from the XBiotech Inc. Annual Report on Form 10-K for the quarter ended December 31, 2022, formatted in Inline Extensive Business Reporting Language (XBRL): (i) condensed consolidated balance sheets, (ii) condensed consolidated statements of operations, (iii) condensed consolidated statements of comprehensive loss, (iv) condensed consolidated statements of shareholders' equity; (v) condensed consolidated statements of cash flows and (vi) notes to condensed consolidated financial statements (detail tagged).
- 104* Cover Page Interactive Data File (embedded within the 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, 2023.

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, 2023 |
| /s/ ANGELA HU Angela Hu, Principal Financial Officer and Principal Accounting Officer | March 15, 2023 |
| /s/ W. THORPE MCKENZIE W. Thorpe McKenzie, Director | March 15, 2023 |
| /s/ JAN-PAUL WALDIN Jan-Paul Waldin, Director | March 15, 2023 |
| /s/ DONALD MACADAM Donald MacAdam, Director | March 15, 2023 |
| /s/ PETER LIBBY Peter Libby, Director | March 15, 2023 |

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

The following summary describes the common shares, no par value, of XBiotech Inc. (the "Company," "we," "our," "us," and "our"), which are the only securities of the Company registered pursuant to Section 12 of the Securities Exchange Act of 1934, as amended.

The following description is a summary and does not purport to be complete. It is subject to and qualified in its entirety by reference to our Articles, which are incorporated by reference as an exhibit to the Annual Report on Form 10-K of which this Exhibit 4.1 is a part. We encourage you to read our Articles and the applicable provisions of the British Columbia Business Corporations Act ("BCBCA") for additional information.

Authorized and Outstanding Stock

Our authorized share capital as described in our Articles consists of an unlimited number of common shares and preferred shares without par value.

As of December 31, 2022, 30,439,275 shares of the Company's common shares were outstanding. No preferred shares are outstanding.

Common Shares

Voting Rights. Holders of common shares are entitled to one vote in respect of each common share held at any meeting of the Company. Except as otherwise provided with respect to any particular series of preferred shares and except as otherwise required by law, the registered holders of preferred shares shall not be entitled as a class to receive notice of or to attend to vote at any meetings of the Company.

Under our Articles, the holders of our common shares will be entitled to one vote for each common share held on all matters submitted to a vote of the shareholders, including the election of directors. Our Articles do not provide for cumulative voting rights. Because of this, the holders of a plurality of our common shares entitled to vote in any election of directors can elect all of the directors standing for election, if they should so choose.

Dividend Rights. Subject to the BCBCA, and subject to the prior rights of any holders of preferred shares, the holders of the common shares in the absolute discretion of the directors, shall be entitled to receive, and the Company shall pay thereon, out of moneys of the Company properly applicable to the payment of dividends, when declared by the directors, only such dividends as may be declared from time to time in respect of the common shares. The preferred shares are entitled to preference over the common shares with respect to the payment of dividends. We have not paid any dividends since our incorporation. At the discretion of our board of directors, we will consider paying dividends in future as our operational circumstances may permit having regard to, among other things, our earnings, cash flow and financial requirements.

Liquidation Rights. Subject to the prior payment to the holders of the preferred shares described below, in the event of the liquidation, dissolution or winding-up of the Company or other distribution of the assets of the Company among its shareholders, the holders of the shares of our common shares shall be entitled to share pro rata in the distribution of the balance of the assets. The preferred shares shall be entitled to a preference over the common shares with respect to the distribution of assets of the Company, whether voluntary or involuntary, or in the event of any other distribution of assets of the Company among its shareholders for the purpose of winding up its affairs; and the preferred stock may be given such other preference not inconsistent with our Articles.

Other Rights. Our common shares have no preemptive rights, no conversion rights, no redemption or sinking fund provisions, and are not liable for further call or assessment.

Listing. Our common shares currently trade on the Nasdaq Global Select Market under the symbol "XBIT."

Anti-Takeover Provisions

Certain Takeover Bid Requirements. Unless such offer constitutes an exempt transaction, an offer made by a person, an "offeror", to acquire outstanding shares of a Canadian entity that, when aggregated with the offeror's holdings (and those of persons or companies acting jointly with the offeror), would constitute 20% or more of the outstanding shares in a class, would be subject to the take-over provisions of Canadian securities laws. The foregoing is a limited and general summary of certain aspects of applicable securities law in the provinces and territories of Canada, all in effect as of the date hereof.

In addition to those takeover bid requirements noted above, the acquisition of our shares may trigger the application of statutory regimes including among others, the Investment Canada Act (Canada) and the Competition Act (Canada).

Limitations on the ability to acquire and hold our common shares may be imposed by the Competition Act (Canada). This legislation permits the Commissioner of Competition, or the Commissioner, to review any acquisition of control over or of a significant interest in us. This legislation grants the Commissioner jurisdiction, for up to one year, after any such acquisition, to challenge this type of acquisition before the Canadian Competition Tribunal on the basis that it would, or would be likely to, substantially prevent or lessen competition in any market in Canada.

This legislation also requires any person who intends to acquire our common shares to file a pre-closing notification with the Canadian Competition Bureau if certain financial thresholds are exceeded and if that person (and their affiliates) would hold more than 20% of our common shares. If a person (and its affiliates) already owns 20% or more of our common shares, a notification must be filed when the acquisition of additional shares would bring that person's holdings to over 50%. Where a notification is required, the legislation prohibits completion of the acquisition until the expiration of a statutory waiting period, unless the Commissioner provides written notice that she does not intend to challenge the acquisition.

The Investment Canada Act requires any person that is a "non-Canadian" (as defined in the Investment Canada Act) who acquires control of an existing Canadian business, where the acquisition of control is not a reviewable transaction, to file a notification with Industry Canada. The Investment Canada Act generally prohibits the implementation of a reviewable transaction unless, after review, the relevant minister is satisfied that the investment is likely to be of net benefit to Canada. Under the Investment Canada Act, the acquisition of control of us (either through the acquisition of our common shares or all or substantially all our assets) by a non-Canadian who is a World Trade Organization member country investor, including a US investor, would be reviewable only if our enterprise value was equal to or greater than a specified amount. Currently, the specified amount for is CAD\$600 million, but will eventually increase to CAD\$1.0 billion. We believe that we are not a cultural business for Investment Canada Act purposes and that the lower threshold for reviews of acquisitions of such businesses does not apply. The threshold amount is subject to an annual adjustment on the basis of a prescribed formula in the Investment Canada Act to reflect changes in Canadian gross domestic product.

The acquisition of a majority of the voting interests of an entity is deemed to be acquisition of control of that entity. The acquisition of less than a majority but one-third or more of the voting shares of a corporation or an equivalent undivided ownership interest in the voting shares of a corporation is presumed to be an acquisition of control of that corporation unless it can be established that, on the acquisition, the corporation is not controlled in fact by the acquirer through the ownership of voting shares. The acquisition of less than one-third of the voting shares of a corporation is deemed not to be an acquisition of control of that corporation.

Under the new national security regime in the Investment Canada Act, review on a discretionary basis may also be undertaken by the federal government in respect of a much broader range of investments by a non-Canadian to "acquire, in whole or in part, or to establish an entity carrying on all or any part of its operations in Canada." The relevant test is whether such an investment by a non-Canadian could be "injurious to national security." The Minister of Industry has broad discretion to determine whether an investor is a non-Canadian and may be subject to national security review. Review on national security grounds is at the discretion of the federal government and may occur on a pre- or post-closing basis, subject to certain limitation provisions. The government has the power in a national security review to direct that the investment not be implemented, to direct that the investor provide undertakings or the investor implement the investment on prescribed terms or conditions and to order the investor to divest itself of the investment.

There is no law, governmental decree or regulation in Canada that restricts the export or import of capital or which would affect the remittance of dividends or other payments by us to non-Canadian holders of our common shares or preferred shares, other than withholding tax requirements.

Our Articles do not contain any change of control limitations with respect to a merger, acquisition or corporate restructuring that involves us.

This summary is not a comprehensive description of relevant or applicable considerations regarding such requirements and, accordingly, is not intended to be, and should not be interpreted as, legal advice to any prospective purchaser and no representation with respect to such requirements to any prospective purchaser is made. Prospective investors should consult their own Canadian legal advisors with respect to any questions regarding securities law in the provinces and territories of Canada.

Actions Requiring a Special Majority. Under the BCBCA and our Articles, certain corporate actions require the approval of a special majority of shareholders, meaning holders of shares representing not less than 66 2/3% of those votes cast in respect of a shareholder vote addressing such matter. Subject to the BCBCA, those items requiring the approval of a special majority generally relate to fundamental changes with respect to our business, and include among others, resolutions: (i) to alter its articles or authorized share structure; (ii) to remove a director before the expiry of his or her term; and (iii) to provide for a sale, lease or exchange of all or substantially all of the Company's property.

Shareholder Proposals. Under the BCBCA, shareholders may make proposals for matters to be considered at the annual general meeting of shareholders. Such proposals must be sent to us in advance of any proposed meeting by delivering a timely written notice in proper form to our registered office in accordance with the requirements of the BCBCA. The notice must include information on the business the shareholder intends to bring before the meeting.

Advance Notice Provisions. Our Articles contain provisions (the "Advance Notice Provisions") which provide that advance notice to the Company must be made and the procedures set out in the Articles must be followed for persons to be eligible for election to the our board of directors. Nomination of persons for election to the board of directors may only be made at an annual meeting of shareholders or at a special meeting of shareholders called for any purpose which includes the election of directors.

Among other things, the Advance Notice Provisions fix a deadline by which holders of record of common shares must submit director nominations to us prior to any annual or special meeting of shareholders and set forth the specific information that a shareholder must include in the written notice to the Company for an effective nomination to occur. No person will be eligible for election as a director of the Company unless nominated in accordance with the provisions of the Advance Notice Provisions.

In the case of an annual meeting of shareholders, notice to us must be made not less than 30 or more than 65 days prior to the date of the annual meeting; provided, however, that if the annual meeting is to be held on a date that is less than 50 days after the date on which the first public announcement of the date of the annual meeting was made, notice may be made not later than the close of business on the 10th day following such public announcement. In the case of a special meeting of shareholders (which is not also an annual meeting), notice to us must be made not later than the close of business on the 15th day following the day on which the first public announcement of the date of the special meeting was made.

The board of directors may, in its sole discretion, waive any requirement of the Advance Notice Provisions.

Limitation of Liability and Indemnification

We are subject to the provisions of Part 5, Division 5 of the BCBCA. Under Section 160 of the BCBCA, we may, subject to Section 163 of the BCBCA:

- (1) indemnify an individual who:
 - (a) is or was a director or officer of the Company;
 - (b) is or was a director or officer of another corporation (i) at a time when such corporation is or was an affiliate of the Company; or (ii) at the Company's request, or
 - (c) at the Company's request, is or was, or holds or held a position equivalent to that of, a director or officer of a partnership, trust, joint venture or other unincorporated entity, and including, subject to certain limited exceptions, the heirs and personal or other legal representatives of that individual (collectively, an "eligible party"), against all eligible penalties to which the eligible party is or may be liable; and

- (2) after final disposition of an eligible proceeding, pay the expenses actually and reasonably incurred by an eligible party in respect of that proceeding, where:
 - (a) "eligible penalty" means a judgment, penalty or fine awarded or imposed in, or an amount paid in settlement of, and eligible proceeding.
 - (b) "eligible proceeding" means a proceeding in which an eligible party or any of the heirs and personal or other legal representatives of the eligible party, by reason of the eligible party being or having been a director or officer of, or holding or having held a position equivalent to that of a director or officer of, the Company or an associated corporation (i) is or may be joined as a party, or (ii) is or may be liable for or in respect of a judgment, penalty or fine in, or expenses related to, the proceeding.
 - (c) "proceeding" includes any legal proceeding or investigative action, whether current, threatened, pending or completed.

Under Section 161 of the BCBCA, and subject to Section 163 of the BCBCA, we must, after the final disposition of an eligible proceeding, pay the expenses actually and reasonably incurred by an eligible party in respect of that proceeding if the eligible party (i) has not been reimbursed for those expenses, and (ii) is wholly successful, on the merits or otherwise, in the outcome of the proceeding or is substantially successful on the merits in the outcome of the proceeding.

Under Section 162 of the BCBCA, and subject to Section 163 of the BCBCA, we may pay, as they are incurred in advance of the final disposition of an eligible proceeding, the expenses actually and reasonably incurred by an eligible party in respect of the proceeding, provided that the Company must not make such payments unless we first receive from the eligible party a written undertaking that, if it is ultimately determined that the payment of expenses is prohibited under Section 163 of the BCBCA, the eligible party will repay the amounts advanced.

Under Section 163 of the BCBCA, we must not indemnify an eligible party against eligible penalties to which the eligible party is or may be liable or pay the expenses of an eligible party in respect of that proceeding under Sections 160, 161 or 162 of the BCBCA, as the case may be, if any of the following circumstances apply:

- if the indemnity or payment is made under an earlier agreement to indemnify or pay expenses and, at the time that the agreement to indemnify or pay expenses was made, the Company was prohibited from giving the indemnity or paying the expenses by the Company's memorandum or Articles;
- if the indemnity or payment is made otherwise than under an earlier agreement to indemnify or pay expenses and, at the time that the indemnity or payment is made, the Company is prohibited from giving the indemnity or paying the expenses by the Company's memorandum or Articles;
- if, in relation to the subject matter of the eligible proceeding, the eligible party did not act honestly and in good faith with a view to the best interests of the Company or the associated corporation, as the case may be; or
- in the case of an eligible proceeding other than a civil proceeding, if the eligible party did not have reasonable grounds for believing that the eligible party's conduct in respect of which the proceeding was brought was lawful.

If an eligible proceeding is brought against an eligible party by or on behalf of the Company or by or on behalf of an associated corporation, we must not either indemnify the eligible party against eligible penalties to which the eligible party is or may be liable, or pay the expenses of the eligible party under Sections 160, 161 or 162 of the BCBCA, as the case may be, in respect of the proceeding.

Under Section 164 of the BCBCA, and despite any other provision of Part 5, Division 5 of the BCBCA and whether or not payment of expenses or indemnification has been sought, authorized or declined under Part 5, Division 5 of the BCBCA, on application of the Company or an eligible party, the Supreme Court of British Columbia may do one or more of the following:

- order us to indemnify an eligible party against any liability incurred by the eligible party in respect of an eligible proceeding;
- order us to pay some or all of the expenses incurred by an eligible party in respect of an eligible proceeding;
- order the enforcement of, or payment under, an agreement of indemnification entered into by us;
- order us to pay some or all of the expenses actually and reasonably incurred by any person in obtaining an order under Section 164 of the BCBCA; or
- make any other order the court considers appropriate.

Section 165 of the BCBCA provides that we may purchase and maintain insurance for the benefit of an eligible party or the heirs and personal or other legal representatives of the eligible party against any liability that may be incurred by reason of the eligible party being or having been a director or officer of, or holding or having held a position equivalent to that of a director or officer of, the Company or an associated corporation.

Under our Articles, and subject to the BCBCA, we must indemnify an eligible party and his or her heirs and legal personal representatives against all eligible penalties to which such person is or may be liable, and we must, after the final disposition of an eligible proceeding, pay the expenses actually and reasonably incurred by such person in respect of that proceeding. Each eligible party is deemed to have contracted with the Company on the terms of the indemnity contained in the Articles.

Under our Articles, and subject to the BCBCA, we may agree to indemnify and may indemnify any person (including an eligible party) against eligible penalties and pay expenses incurred in connection with the performance of services by that person for us.

Under our Articles, and subject to the BCBCA, we may advance expenses to an eligible party.

Pursuant to our Articles, the failure of an eligible party to comply with the BCBCA or the Articles does not, of itself, invalidate any indemnity to which he or she is entitled under the Articles.

Under our Articles, we may purchase and maintain insurance for the benefit of an eligible person (or his or her heirs or legal personal representatives) against any liability incurred by him or her as a director, officer or person who holds or held such equivalent position.

Transfer Agent and Registrar

The Transfer Agent and Registrar for shares of our common shares is American Stock Transfer & Trust Company, LLC ("AST"). The address for AST is 6201 15th Avenue, Brooklyn, New York 11219 and its telephone number is (718) 921-8206.

XBiotech Inc. 2015 Equity Incentive Plan

Incentive Share Option Agreement

This Incentive Share Option Agreement ("Agreement") is made and entered into, subject to shareholder approval, by and between XBiotech Inc. (the "Company") and ###PARTICIPANT_NAME### ("Participant") to reflect the terms of an option granted to Participant under the XBiotech Inc. 2015 Equity Incentive Plan ("Plan") by action of the President & Chief Executive Officer of the Company administering the Plan pursuant to delegation of authority under section 3.1 of the Plan on ###GRANT_DATE### ("Grant Date") in consideration of services rendered or to be rendered by the Participant.

- 1. <u>Grant of Option.</u> Subject to the terms and conditions set forth in the Plan and herein as well as shareholder approval, the Company grants to Participant an option ("Option") to purchase a total of ###TOTAL_AWARDS### Common Shares of the Company ("Shares") at a price of ###GRANT_PRICE### per Share ("Exercise Price"), which is not less than [100]% of the Fair Market Value thereof on the Grant Date. The grant of this Option does not create any contractual right or other right of Participant to receive any options or other awards under the Plan in the future.
- 2. <u>Term.</u> Except as otherwise provided pursuant to Section 4 herein or the Plan, this Option shall expire on the ten-year anniversary of the Grant Date ("Expiration Date").
- 3. <u>Vesting.</u>
- (a) Subject to the Participant's continuing employment or service with the Company (or a parent or subsidiary of the Company) and the terms and conditions set forth in the Plan and herein, this Option shall vest and become exercisable as follows:

###VEST SCHEDULE TABLE###

For purposes of this Agreement, the "Vesting Commencement Date" shall mean ###ALTERNATIVE_VEST_BASE_DATE###.

- (b) The Participant must remain continuously employed by the Company (or a parent or subsidiary of the Company) from the Grant Date (or if earlier, the Vesting Commencement Date) to the applicable vesting date for vesting to occur. There shall be no proportionate or partial vesting in the period prior to each vesting date and all vesting shall occur only on the appropriate vesting date.
- (c) The right of exercise shall be cumulative so that to the extent this Option is not exercised in any period to the maximum extent permissible it shall continue to be exercisable, in whole or in part, with respect to all Shares for which it is vested until the earlier of the Expiration Date or the termination of this Option under Section 4 hereof or the Plan.
- 4. <u>Termination of Option</u>. In general, the right to purchase Stock under this Option shall lapse on the Expiration Date. However, this Option shall terminate sooner in the circumstances described in this Section 4.
- (a) Termination for Reasons Other Than Cause, Death or Disability. If the Participant's continuous service as an employee or officer of the Company (or a parent or subsidiary of the Company) terminates for any reason other than death, Disability or Cause, the Participant may exercise the vested portion of this Option only within the period of time ending on the earlier of: (i) the date three months following the termination of his or her continuous service or (ii) the Expiration Date. Thereafter this Option shall terminate and cease to be exercisable. Notwithstanding, if at any time during this period the Participant violates the non-competition or confidentiality provisions of any employment contract, confidentiality and nondisclosure agreement or other agreement between the Participant and the Company (or a parent or subsidiary of the Company), his or her right to exercise this Option shall immediately terminate and cease to be exercisable upon such violation.
- (b) <u>Termination Due Disability</u>. If termination of the Participant's continuous service with the Company (or a parent or subsidiary of the Company) is due to his or her total disability (as defined under the Plan) the vested portion of this Option shall remain exercisable only within the period of time ending on the earlier of: (i) the date 12 months following the Participant's termination of his or her continuous service due to his or her total disability or (ii) the Expiration Date. Thereafter this Option shall terminate and cease to be exercisable.

- (c) <u>Termination Due to Death</u>. If termination of the Participant's continuous service as an employee or officer of the Company (or a parent or subsidiary of the Company) is due to his or her death or if the Participant's death occurs within three months after his or her continuous service with the Company (or a parent or subsidiary of the Company) terminates, the vested portion of this Option shall remain exercisable only within the period of time ending on the earlier of: (i) the date 365 days after the Participant's death or (ii) the Expiration Date. Thereafter this Option shall terminate and cease to be exercisable.
- (d) Termination for Cause. If termination of the Participant's continuous service is by the Company (or a parent or subsidiary of the Company) for Cause, the entire Option (vested and unvested portions) shall immediately terminate and cease to be exercisable. If the Participant is party to an employment or severance agreement with the Company that contains a definition of "cause" for termination of employment, "Cause" shall have the meaning ascribed to such term in such agreement. Otherwise, "Cause" shall mean willful misconduct by the Participant or willful failure by the Participant to perform his or her responsibilities to the Company (or a parent or subsidiary of the Company, including, without limitation, breach by the Participant of any provision of any employment, consulting, advisory, nondisclosure, non-competition or other similar agreement between the Participant and the Company (or a parent or subsidiary of the Company), as determined by the Company, which determination shall be conclusive. The Participant shall be considered to have been discharged for Cause if the Company determines, within 30 days after the Participant's resignation, that discharge for cause was warranted.

5. Exercise of Option.

- (a) Notice of Exercise. To exercise this Option (or any vested portion thereof) the Participant (or in the case of exercise after the Participant's death or total disability, the Participant's executor, administrator, legal guardian or the person who acquired the right to exercise this Option by bequest or inheritance or such other person designated to exercise this Option upon the Participant's death or incapacity, as applicable) must submit a completed Notice of Stock Option Exercise in substantially the form attached hereto as Exhibit A, to the Company at its principal office along with a copy of this Agreement and full payment of the Exercise Price. The Participant may purchase less than the number of vested Shares covered hereby, provided that no partial exercise of this Option may be for any fractional Share or for fewer than ten whole Shares. If a person other than the Participant exercises this Option, then such person must also submit documentation reasonably acceptable to the Company substantiating his or her legal right to exercise this Option
- (b) <u>Payment of Exercise Price</u>. Subject to any restrictions under the Plan, the Exercise Price may be paid in any combination of the following:
- (i) in cash or by certified or bank check; or
- (ii) through a cashless exercise program established with a broker.
- (c) <u>Withholding</u>. No Shares will be issued pursuant to the exercise of this Option unless and until the Participant pays to the Company, or makes an arrangement satisfactory to the Company for payment of, any federal, state or local withholding taxes required by law to be withheld by the Company (or a parent or subsidiary of the Company) in connection with the exercise of this Option or the sale or other disposition of the Shares issued upon exercise of this Option. The Company (or a parent or subsidiary) has the right to withhold any applicable withholding from any compensation paid to the Participant.
- 6. <u>Issuance of Shares</u>. Upon satisfaction of the requirements under Section 5 herein, the Company shall issue the Shares registered in the name of the Participant (or the Participant's permitted assignee or legal representative) as evidenced by stock certificates with the appropriate legends affixed thereto and make the appropriate entry on the books of the Company or of a duly authorized transfer agent. Notwithstanding any provision herein to the contrary, the exercise of this Option and the issuance and transfer of Shares shall be subject to compliance by the Company and the Participant with all applicable requirements of federal and state securities laws and with all applicable requirements of any stock exchange on which the Company's Common Shares may be listed. No Shares shall be issued pursuant to this Option unless and until any then applicable requirements of state or federal laws and regulatory agencies have been fully complied with to the satisfaction of the Company.

7. <u>Incentive Stock Option Status</u>.

(a) Section 422 Requirements. This Option is intended to qualify as an "incentive stock option" under Section 422 of the Code and any regulations promulgated thereunder. However, the Company makes no representation or guarantee that this Option will qualify as an incentive stock option. This Option will not qualify as an "incentive stock option," if, among other events, (i) the Participant disposes of the Shares acquired upon exercise of this Option within two years from the Grant Date or one year after such Shares were acquired pursuant to exercise of this Option; (ii) except in the event of the Participant's death or total disability (as described in Section 4 above), the Participant has not been in the continuous service of the Company (or a parent or a subsidiary of the Company) as an employee or officer during the period beginning on the Grant Date and ending on the day that is three (3) months before the date of exercise this Option; or (iii) to the extent the aggregate fair market value of the shares subject to all "incentive stock options" held by the Participant which become exercisable for the first time in any calendar year (under all plans of the Company, a parent or a subsidiary) exceeds \$100,000.

- (b) <u>Disqualifying Disposition</u>. To the extent that any share does not qualify as an "incentive stock option," it shall not affect the validity of such Shares and shall constitute a separate non-qualified stock option. In the event that the Participant disposes of the Shares acquired upon exercise of this Option within two years from the Grant Date or one year after such Shares were acquired pursuant to exercise of this option, the Participant must deliver to the Company, within seven (7) days following such disposition, a written notice specifying the date on which such Shares were disposed of, the number of Shares so disposed, and, if such disposition was by a sale or exchange, the amount of consideration received. Further, Participant agrees to provide Company with any other information relating to such disposition as it may reasonably require for tax purposes.
- 8. <u>Nontransferability of Option</u>. Except as otherwise provided herein, this Option may not be sold, assigned, transferred, pledged or otherwise encumbered by the Participant, either voluntarily or by operation of law, except by will or the laws of descent and distribution. No assignment or transfer of this Option, or the rights represented thereby, by operation of law or otherwise (except to a designated beneficiary, upon death, by will or the laws of descent or distribution) shall vest in the assignee or transferee any interest or rights herein; but rather, upon such attempted assignment or transfer this Option in violation of this Section 8 shall be void.
- 9. <u>No Rights as a Shareholder</u>. The Participant shall have no rights as a shareholder of the Company with respect to any Shares covered by this Option unless and until the Participant has become the holder of record of such Shares and no adjustment shall be made for dividends or other property, distributions or other rights in respect of any such Shares, except as otherwise specifically provided for in the Plan.
- 10. <u>No Obligation to Continue Employment</u>. This Agreement is not an agreement of employment. This Agreement does not guarantee that the Company will employ the Participant for any specific time period, nor does it modify in any respect the Company's right to terminate or modify the Participant's employment or compensation.
- 11. <u>Governing Law.</u> All questions concerning the construction, validity and interpretation of this Agreement shall be governed by, and construed in accordance with, the laws of the State of Delaware, without regard to the choice of law principles thereof.
- 12. <u>Section 409A</u>. The intent of the parties is that this Option is exempt from the provisions of Section 409A of the Code and, accordingly, to the maximum extent permitted, this Agreement shall be interpreted to be limited, construed and interpreted in accordance with such intent. In no event whatsoever shall the Company be liable for any additional tax, interest or penalties that may be imposed on Participant by Section 409A of the Code or any damages for failing to comply with Section 409A of the Code hereunder or otherwise.
- 13. <u>Severability</u>. The invalidity or unenforceability of any provision in this Agreement shall not affect the validity or enforceability of any other provision of this Agreement and each provision of this Agreement shall be severable and enforceable to the extent permitted by law.
- 14. <u>Entire Agreement</u>. This Agreement and the Plan constitute the entire agreement between the parties with regard to the subject matter hereof. This Agreement supersedes all previous agreements between the parties regarding such subject matter, and no agreements, representations or warranties regarding the subject matter hereof exist between the parties, other than those set forth herein.
- 15. <u>Successors and Assigns</u>. The Company may assign any of its rights under this Agreement. This Agreement will be binding upon and inure to the benefit of the successors and assigns of the Company. Subject to the restrictions on transfer set forth herein, this Agreement will be binding upon the Participant and the Participant's beneficiaries, executors, administrators and the person(s) to whom this Option may be transferred by will or the laws of descent or distribution.

| 16. <u>Amendment</u> . The Company has the right to amend this Agreement provided that no such amendment shall adversely affect the Participant's material rights under this Agreement without the Participant's consent, unless such amendment is necessary for the Option to comply with applicable federal or state law. |
|---|
| 17. <u>No Third Party Beneficiaries</u> . Nothing in this Agreement is intended to confer any rights or remedies on any persons other than the Parties and their respective successors and assigns. Nothing in this Agreement is intended to relieve or discharge the obligation or liability of third persons to any party to this Agreement. No provision of this Agreement shall give any third person any right of subrogation or action over or against any party to this Agreement. |
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18. <u>Provisions of the Plan</u>. This Option is subject to the provisions of the Plan, including any amendments thereto). Any capitalized terms used herein but not defined shall have the meaning ascribed to them in the Plan. In the event of a conflict between any term or provision contained herein and a term or provision of the Plan, the applicable terms and provisions of the Plan shall govern.

IN WITNESS WHEREOF, the Company has caused this Agreement to be executed under its corporate seal by its duly authorized officer.

XBiotech Inc.

By: ###JOHNSIMARD###

Name: John Simard Title: President & CEO

PARTICIPANT'S ACCEPTANCE

I, ###PARTICIPANT_NAME###, hereby accept the foregoing option award agreement and agree to the terms and conditions thereof. Furthermore, I hereby acknowledge having received and read a copy of the Company's 2015 Equity Incentive Plan and agree to comply with it and all applicable laws and regulations. By clicking accept I agree to the terms and conditions.

PARTICIPANT: ###PARTICIPANT_NAME###

Address: ###HOME_ADDRESS###

XBiotech Inc. 2015 Equity Incentive Plan Nonqualified Share Option Agreement

This Nonqualified Share Option Agreement ("Agreement") is made and entered into, subject to shareholder approval, by and between XBiotech Inc. (the "Company") and ###PARTICIPANT_NAME### ("Participant") to reflect the terms of an option granted to Participant under the XBiotech Inc. 2015 Equity Incentive Plan ("Plan") by action of the Board of Directors of the Company on ###GRANT_DATE### ("Grant Date") in consideration of services rendered or to be rendered by the Participant.

- 1. <u>Grant of Option.</u> Subject to the terms and conditions set forth in the Plan and herein as well as shareholder approval, the Company grants to Participant an option ("Option") to purchase a total of ###TOTAL_AWARDS### Common Shares of the Company ("Shares") at a price of ###GRANT_PRICE### per Share ("Exercise Price"), which is not less than 100% of the Fair Market Value thereof on the Grant Date. The grant of this Option does not create any contractual right or other right of Participant to receive any options or other awards under the Plan in the future.
- 2. <u>Term.</u> Except as otherwise provided pursuant to Section 4 herein or the Plan, this Option shall expire on the ten-year anniversary of the Grant Date ("Expiration Date").
- 3. <u>Vesting.</u>
- (a) Subject to the Participant's continuing employment or service with the Company (or a parent or subsidiary of the Company) and the terms and conditions set forth in the Plan and herein, this Option shall vest and become exercisable as follows:

###VEST_SCHEDULE_TABLE###

For purposes of this Agreement, the "Vesting Commencement Date" shall mean ###GRANT_DATE### .

- (b) The Participant must remain continuously employed by the Company (or a parent or subsidiary of the Company) from the Grant Date (or if earlier, the Vesting Commencement Date) to the applicable vesting date for vesting to occur. There shall be no proportionate or partial vesting in the period prior to each vesting date and all vesting shall occur only on the appropriate vesting date.
- (c) The right of exercise shall be cumulative so that to the extent this Option is not exercised in any period to the maximum extent permissible it shall continue to be exercisable, in whole or in part, with respect to all Shares for which it is vested until the earlier of the Expiration Date or the termination of this Option under Section 4 hereof or the Plan.
 - 1. <u>Termination of Option</u>. In general, the right to purchase Stock under this Option shall lapse on the Expiration Date. However, this Option shall terminate sooner in the circumstances described in this Section 4.
- (a) <u>Termination Generally.</u> Except as otherwise provided in this Section 4, if the Participant's continuous service as an employee, officer, director or Consultant of the Company (or a parent or subsidiary of the Company) terminates for any reason, the Participant may exercise the vested portion of this Option only within the period of time ending on the earlier of: (i) the date 90 days after the termination of Participant's continuous service or (ii) the Expiration Date. Thereafter, this Option shall terminate and cease to be exercisable. Notwithstanding, if at any time during this period the Participant violates the non-competition or confidentiality provisions of any employment or services contract, confidentiality and nondisclosure agreement or other agreement between the Participant and the Company (or a parent or subsidiary of the Company), Participant's right to exercise this Option shall immediately terminate and cease to be exercisable upon such violation.
- (b) <u>Termination Due to Disability</u>. If termination of the Participant's continuous service as an employee, officer, director or Consultant of the Company (or a parent or subsidiary of the Company) is due to his or her disability, the vested portion of this Option shall be exercisable by Participant only within the period of time ending on the earlier of: (i) the date 365 days after the termination of Participant's continuous service due to his disability or (ii) the Expiration Date. Thereafter this Option shall terminate and cease to be exercisable.
- (c) <u>Termination Due to Retirement</u>. If termination of the Participant's continuous service as an employee or officer of the Company (or a parent or subsidiary of the Company) is due to his or her Retirement, the vested portion of this Option shall be exercisable by the Participant only within the period of time ending on the earlier of: (i) the date 180 days after the Participant's termination of his or her continuous service due to his or her Retirement or (ii) the Expiration Date. Thereafter this Option shall terminate and cease to be exercisable.

- (d) <u>Termination Due to Death</u>. If termination of the Participant's continuous service as an employee, officer, director or Consultant of the Company (or a parent or subsidiary of the Company) is due to his or her death or if the Participant's death occurs within three months after his or her continuous service with the Company (or a parent or subsidiary of the Company) terminates, the vested portion of this Option shall remain exercisable only within the period of time ending on the earlier of: (i) the date 365 days after the Participant's death or (ii) the Expiration Date. Thereafter this Option shall terminate and cease to be exercisable.
- (e) <u>Termination for Cause</u>. If termination of the Participant's continuous service is by the Company (or a parent or subsidiary of the Company) for Cause, the entire Option (vested and unvested portions) shall immediately terminate and cease to be exercisable. If the Participant is party to an employment or severance agreement with the Company that contains a definition of "cause" for termination of employment, "Cause" shall have the meaning ascribed to such term in such agreement. Otherwise, "Cause" shall mean willful misconduct by the Participant or willful failure by the Participant to perform his or her responsibilities to the Company (or a parent or subsidiary of the Company, including, without limitation, breach by the Participant of any provision of any employment, consulting, advisory, nondisclosure, non-competition or other similar agreement between the Participant and the Company (or a parent or subsidiary of the Company), as determined by the Company, which determination shall be conclusive. The Participant shall be considered to have been discharged for Cause if the Company determines, within 30 days after the Participant's resignation, that discharge for cause was warranted.

1. Exercise of Option.

- (a) Notice of Exercise. To exercise this Option (or any vested portion thereof) the Participant (or in the case of exercise after the Participant's death or total disability, the Participant's executor, administrator, legal guardian or the person who acquired the right to exercise this Option by bequest or inheritance or such other person designated to exercise this Option upon the Participant's death or incapacity, as applicable) must submit a completed Notice of Stock Option Exercise in substantially the form attached hereto as Exhibit A, to the Company at its principal office along with a copy of this Agreement and full payment of the Exercise Price. The Participant may purchase less than the number of vested Shares covered hereby, provided that no partial exercise of this Option may be for any fractional Share or for fewer than ten whole Shares. If a person other than the Participant exercises this Option, then such person must also submit documentation reasonably acceptable to the Company substantiating his or her legal right to exercise this Option
- (b) Payment of Exercise Price. Subject to any restrictions under the Plan, the Exercise Price may be paid in any combination of the following:
- (i) in cash or by certified or bank check; or
- (ii) through a cashless exercise program established with a broker.
- (c) <u>Withholding</u>. No Shares will be issued pursuant to the exercise of this Option unless and until the Participant pays to the Company, or makes an arrangement satisfactory to the Company for payment of, any federal, state or local withholding taxes required by law to be withheld by the Company (or a parent or subsidiary of the Company) in connection with the exercise of this Option or the sale or other disposition of the Shares issued upon exercise of this Option. The Company (or a parent or subsidiary) has the right to withhold any applicable withholding from any compensation paid to the Participant.
 - 1. <u>Issuance of Shares</u>. Upon satisfaction of the requirements under Section 5 herein, the Company shall issue the Shares registered in the name of the Participant (or the Participant's permitted assignee or legal representative) as evidenced by stock certificates with the appropriate legends affixed thereto and make the appropriate entry on the books of the Company or of a duly authorized transfer agent. Notwithstanding any provision herein to the contrary, the exercise of this Option and the issuance and transfer of Shares shall be subject to compliance by the Company and the Participant with all applicable requirements of federal and state securities laws and with all applicable requirements of any stock exchange on which the Company's Common Shares may be listed. No Shares shall be issued pursuant to this Option unless and until any then applicable requirements of state or federal laws and regulatory agencies have been fully complied with to the satisfaction of the Company.

- 2. <u>Nontransferability of Option</u>. Except as otherwise provided herein, this Option may not be sold, assigned, transferred, pledged or otherwise encumbered by the Participant, either voluntarily or by operation of law, except by will or the laws of descent and distribution. No assignment or transfer of this Option, or the rights represented thereby, by operation of law or otherwise (except to a designated beneficiary, upon death, by will or the laws of descent or distribution) shall vest in the assignee or transferee any interest or rights herein; but rather, upon such attempted assignment or transfer this Option in violation of this Section 7 shall be void.
- 3. <u>No Rights as a Shareholder</u>. The Participant shall have no rights as a shareholder of the Company with respect to any Shares covered by this Option unless and until the Participant has become the holder of record of such Shares and no adjustment shall be made for dividends or other property, distributions or other rights in respect of any such Shares, except as otherwise specifically provided for in the Plan.
- 4. No Obligation to Continue Employment or Service. Neither the Plan nor this Agreement shall confer upon the Participant any right to be retained by the Company (or a parent or subsidiary of the Company) as an employee, officer, director or Consultant. Further, nothing in the Plan or this Agreement shall be construed to limit the discretion of the Company (or a parent or subsidiary of the Company) to terminate the Participant's employment or service at any time.
- 5. <u>Governing Law.</u> All questions concerning the construction, validity and interpretation of this Agreement shall be governed by, and construed in accordance with, the laws of the State of Delaware, without regard to the choice of law principles thereof.
- 6. <u>Section 409A</u>. The intent of the parties is that this Option is exempt from the provisions of Section 409A of the Code and, accordingly, to the maximum extent permitted, this Agreement shall be interpreted to be limited, construed and interpreted in accordance with such intent. In no event whatsoever shall the Company be liable for any additional tax, interest or penalties that may be imposed on Participant by Section 409A of the Code or any damages for failing to comply with Section 409A of the Code hereunder or otherwise.
- 7. <u>Severability</u>. The invalidity or unenforceability of any provision in this Agreement shall not affect the validity or enforceability of any other provision of this Agreement and each provision of this Agreement shall be severable and enforceable to the extent permitted by law.
- 8. <u>Entire Agreement</u>. This Agreement and the Plan constitute the entire agreement between the parties with regard to the subject matter hereof. This Agreement supersedes all previous agreements between the parties regarding such subject matter, and no agreements, representations or warranties regarding the subject matter hereof exist between the parties, other than those set forth herein.
- 9. <u>Successors and Assigns</u>. The Company may assign any of its rights under this Agreement. This Agreement will be binding upon and inure to the benefit of the successors and assigns of the Company. Subject to the restrictions on transfer set forth herein, this Agreement will be binding upon the Participant and the Participant's beneficiaries, executors, administrators and the person(s) to whom this Option may be transferred by will or the laws of descent or distribution.
- 10. <u>Amendment</u>. The Company has the right to amend this Agreement provided that no such amendment shall adversely affect the Participant's material rights under this Agreement without the Participant's consent, unless such amendment is necessary for the Option to comply with applicable federal or state law.
- 11. No Third Party Beneficiaries. Nothing in this Agreement is intended to confer any rights or remedies on any persons other than the Parties and their respective successors and assigns. Nothing in this Agreement is intended to relieve or discharge the obligation or liability of third persons to any party to this Agreement. No provision of this Agreement shall give any third person any right of subrogation or action over or against any party to this Agreement.
- 12. <u>Provisions of the Plan</u>. This Option is subject to the provisions of the Plan, including any amendments thereto). Any capitalized terms used herein but not defined shall have the meaning ascribed to them in the Plan. In the event of a conflict between any term or provision contained herein and a term or provision of the Plan, the applicable terms and provisions of the Plan shall govern.

IN WITNESS WHEREOF, the Company has caused this Agreement to be executed under its corporate seal by its duly authorized officer.

XBiotech Inc.

By: ###JOHNSIMARD###

Name: John Simard Title: President & CEO

PARTICIPANT'S ACCEPTANCE

| I, ###PARTICIPANT_NAME###, hereby accept the foregoing option award agreement and agree to the terms and conditions thereof. Furthermore, I | |
|---|----|
| hereby acknowledge having received and read a copy of the Company's 2015 Equity Incentive Plan and agree to comply with it and all applicable lav | ٧S |
| and regulations. By clicking accept I agree to the terms and conditions. | |

PARTICIPANT: ###PARTICIPANT_NAME###

Address: ###HOME_ADDRESS###



Board Member Agreement

This Agreement (this "Agreement"), dated as of the 27th day of February 2018, is between, Jan-Paul Waldin, an individual having a residence at 381-32 Stadium Rd., Toronto, Ontario, , (the "Board Director"), and XBiotech Inc., a Canadian corporation with a place of business at 300-1055 West Hastings Street, Vancouver BC V6E 2E9 Canada (the "Company").

WHEREAS, the parties desire to enter into this Agreement setting forth the terms and conditions of the Board Director with the Company;

NOW, THEREFORE, the parties agree as follows:

- Effective Date. This Agreement shall be effective as of the 27th day of February, 2018 (the "Effective Date").
- Term. Subject to the provisions of Section 13 of this Agreement, this Agreement shall commence on the Effective Date and be effective until the date terminated by either the Company or Board Director (the "Term").
- Position. During the Term, the Board Director shall act as a "Board Member" to the Company.
- 4. <u>Duties and Reporting Relationship.</u> During the Term, the Board Director shall be generally available for mutually agreed times during business hours. The Board Director agrees that they shall represent the Company as a "Board Member". Such representations may be made by the Company in SEC filings, during Presentations, Business Plans, on the Company Website, or any other place deemed fit by the Company. The Company may request that you participate in discussions, as suitable to your schedule and availability, with third parties from time to time. You will be asked to chair the Company's compensation committee.
- 5. Compensation: On the effective date of this agreement, Jan-Paul Waldin (the "Option Holder") will be granted non-qualified stock options under the Company's 2015 Equity Incentive Plan (the "Plan") to purchase 25,000 shares of the Company's common stock, and an additional 12,500 options will be granted on or about the date of the Company's annual stockholders meeting. During Option Holder's service as a Board Member in years following 2018, the Option Holder will be granted 25,000 options annually on or about the date of the Company's annual stockholders meeting. All granted options will be exercisable at a price equal to the closing price of the Company's common stock, as reported by NASDAQ, on the date of grant, and vest in two equal installments occurring six months and 12 months following the date of grant, subject to continued service as a Director (the "Options"). The Options shall expire ten years from the date of grant, unless terminated earlier in accordance with the Plan or the Option Holder's stock option agreement. In accordance with the Plan, the Options will remain exercisable for 90 days after the date of the Option Holders termination without cause or resignation.
- 6. Engagement: The Board Director will be compensated for services provided by telephone, in person meetings, time spent on written work, as well as time spent traveling to or from meetings/events. Performance of these duties requires that the Board Director is formally requested to provide these services. A formal request is preferably in the format of a written document/email, but may also include verbal requests that have been clearly discussed between both parties.
- 7. <u>Business Expense</u>. The Board Director shall be reimbursed for all ordinary and necessary business expenses incurred by the Board Director in connection with his agreement upon timely submission to the Company of receipts and other documentation as required by the Internal Revenue Code of 1986, as amended, and in conformance with the Company's normal expense reimbursement policies and procedures. Executive shall be entitled to reimbursement at first class commercial airline rates for transcontinental travel.



- Indemnification and Insurance. Exhibit A hereto, which is hereby incorporated herein as
 if set forth herein, sets forth certain agreements of the parties hereto in respect of
 indemnification and insurance.
- 9. <u>Termination of the Agreement</u>. The Board Director or the Company may terminate this agreement at any time for any reason. The Agreement hereunder shall automatically terminate upon the death of the Board Director. Any purported termination of the Board Director's agreement by the Company or by the Board Director shall be communicated by written notice of termination to the other party hereto.

10. Representation and Warranties.

- a. The Company represents and warrants that this Agreement has been authorized by the Company and is a valid and binding agreement of the Company enforceable against it in accordance with its terms.
- b. The Board Director represents and warrants that he is not a party to any agreement or instrument which would prevent him from entering into or performing his duties under this Agreement.
- 11. <u>Confidentiality</u>. The Board Director agrees to be subject to the Company's reasonable policies concerning Confidentiality and Non-Disclosure as in effect from time to time. The Company agrees that nothing herein or therein shall prevent the Board Director from rendering services in any capacity to any other person or business from time to time, subject to the compliance with any confidentiality and non-disclosure obligations, to the Board Director's obligations as a fiduciary of the Company and to applicable law.

12. Successors; Binding Agreement.

- a. This Agreement shall not be assignable by the Board Director.
- b. This Agreement is a personal contract and the rights and interests of the Board Director hereunder may not be sold, transferred, assigned, pledged, encumbered, or hypothecated by him, except as otherwise expressly permitted by the provisions of this Agreement. This Agreement shall inure to the benefit of and be enforceable by the Board Director and his personal or legal representatives, executors, administrators, successors, heirs, distributes, devisees and legatees. If the Board Director should die while any amount would still be payable to him hereunder had the Board Director continued to live, all such amounts, unless otherwise provided herein, shall be paid in accordance with the terms of this Agreement to his devisee, legatee or other designee or, if there is no such designee, to his estate.
- c. The obligations of the Company hereunder may not be assigned by the Company without the prior written consent of the Board Director. This Agreement shall be binding upon and be enforceable against the Company's successors (including any direct or indirect successor by purchase, merger, consolidation, or otherwise to all or substantially all of the business and/or assets of the Company) and assigns and against the Board Director's personal and legal representatives.
- 13. Entire Agreement. This Agreement contains all the understandings between the parties hereto pertaining to the matters referred to herein, and on the Effective Date shall supersede all undertakings and agreements, whether oral or in writing, previously entered into by them with respect hereto. The Board Director represents that, in executing this Agreement, he does not rely and has not relied upon any representation or statement not set forth herein made by the Company with regard to the subject matter, bases or effect of this Agreement or otherwise.
- Amendment or Modification; Waiver. No provision of this Agreement may be amended or waived unless such amendment or waiver is agreed to in writing, signed by the Board



Director and by a duly authorized officer of the Company. No waiver by any party hereto of any breach by another party hereto of any condition or provision of this Agreement to be performed by such other party shall be deemed a waiver of a similar or dissimilar condition or provision at the same time, any prior time or any subsequent time.

15. Notices. Any notice to be given hereunder shall be in writing and shall be deemed given when delivered personally, sent by courier or telecopy or registered or certified mail, postage prepaid, return receipt requested, addressed to the party concerned at the address indicated below or to such other address as such party may subsequently give notice of hereunder in writing:

To the Board Director at:

Suite 3000 TD Centre North Tower 77 King Street West, Toronto, Ontario, M5K 1G8

CANADA

To the Company at: Attention: John Simard, President

& CEO

XBiotech USA, Inc. 8201 E Riverside Dr. Bldg. 4 Ste. 100 Austin, TX 78744

Any Notice delivered personally or by courier under this Section 12 shall be deemed given on the date delivered and any notice sent by telecopy or registered or certified mail, postage paid, return receipt requested, shall be deemed given on the date telecopied or mailed.

- 16. Severability. If any provision of this Agreement or the application of any such provision to any party or circumstances shall be determined by any court of competent jurisdiction to be invalid and unenforceable to any extent, the remainder of this Agreement or the application of such provision to such person or circumstances other than those to which it is so determined to be invalid and unenforceable, shall not be affected thereby, and each provision hereof shall be validated and shall be enforced to the fullest extent permitted by law.
- Survivorship. The respective rights and obligations of the parties hereunder shall survive any termination of this Agreement to the extent necessary to the intended preservation of such rights and obligations.
- 18. Governing Law and Jurisdiction. This Agreement will be governed by and construed in accordance with the laws of the State of Delaware, without regard to its conflicts of the laws principles. Each of the parties to this Agreement agrees that the courts of the States of Delaware and New York shall have exclusive jurisdiction to hear and determine any claim, suit, action or proceeding, and to settle any disputes, which may arise out of or are in any way related to or in connection with this Agreement.
- Headings. All descriptive headings of the sections and paragraphs in this Agreement are intended solely for convenience, and no provision of this Agreement is to be construed by reference to the heading of any section or paragraph
- 20. Taxes. The parties agree to cooperate in respect of tax withholding and reporting consequences of the arrangements described herein. The parties acknowledge that there is no U.S. federal tax withholding requirement applicable under current law to the compensation described herein. The Company agrees to facilitate, to the extent reasonably practical, the performance of the Board Director's services in a manner that minimizes the Board Director's U.S. tax obligations.



Counterparts. This Agreement may be executed and delivered, including by facsimile transmission or by electronic transmission in Adobe portable document format (or a "PDF file"), in counterparts, each of which shall be deemed an original, and all of which taken together shall constitute one and the same instrument.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the date first above written.

By: _____ Jan-Paul Waldin

John Simard

President & CEO



EXHIBIT A

1. Definitions. As used in this Exhibit:

- a. "<u>Disinterested Director</u>" with respect to any request by the Board Director for indemnification or advancement of expenses hereunder shall mean a director of the Company who neither is nor was a party to the Proceeding (as defined below) in respect of which indemnification or advancement is being sought by the Board Director.
- b. The term "Expenses" shall mean any expense, liability or loss, including, without limitation, damages, judgments, fines, penalties, settlements (if, and only if, such settlement is approved in advance by the Company, which approval shall not be unreasonably withheld) and costs, attorneys' fees and disbursements and costs of attachment or similar bond, investigations, liabilities, losses, taxes, any expense paid or incurred in connection with investigating, defending, being a witness in, participating in (including on appeal), or preparing for any of the foregoing in, any Proceeding, and any taxes, interests, assessments or other charges imposed as a result of the actual or deemed receipt of any payment under this Exhibit.
- c. The term "Independent Legal Counsel" shall mean any firm of attorneys that is reasonably selected by the Board, so long as such firm is not presently representing and has not in the preceding five (5) years represented the Company, the Company's subsidiaries or affiliates, the Board Director, any entity controlled by the Board Director, or any party adverse to the Company in any matter material to any such party (other than with respect to matters concerning the Board Director under this Exhibit, or of other Board Directors under similar indemnification Exhibits). Notwithstanding the foregoing, the term "Independent Legal Counsel" shall not include any person who, under applicable standards of professional conduct then prevailing, would have a conflict of interest in representing either the Company or the Board Director in an action to determine the Board Director's right to indemnification or advancement of expenses under this Exhibit, the Company's Articles of Association (the "Articles"), applicable law or otherwise.
- d. The term "Proceeding" shall mean any threatened, pending or completed action, suit, arbitration, alternate dispute resolution mechanism, investigation, inquiry, hearing or any other proceeding (including, without limitation, an appeal therefrom), formal or informal, whether brought in the name of the Company or otherwise, whether of a civil, criminal, administrative or investigative nature, and whether by, in or involving a court or an administrative, other governmental or private entity or body (including, without limitation, an investigation by the Company or its Board), in which the Board Director was, is or will be involved as a party or otherwise, by reason of (i) the fact that the Board Director is or was a director (or a director appointee) of the Company, or is or was serving at the request of the Company as an agent of another enterprise, (ii) any actual or alleged act or omission or neglect or breach of duty, including, without limitation, any actual or alleged error or misstatement or misleading statement, which the Board Director commits or suffers while acting in any such capacity, or (iii) the Board Director attempting to establish or establishing a right to indemnification or advancement of expenses pursuant to this Exhibit, the Articles, applicable law or otherwise, in each case whether or not the Board Director is acting or serving in any such capacity at the time any liability or expense is incurred for which indemnification can be provided under this Exhibit.
- e. The phrase "serving at the request of the Company as an agent of another enterprise" or any similar terminology shall mean, unless the context otherwise requires, serving at the request of the Company as a director, officer, employee or agent of another corporation, partnership, joint venture, limited liability company, trust, employee benefit or welfare plan or other enterprise, foreign or domestic. The phrase "serving at the request of the Company" shall include, without limitation, any service as a director or an executive officer of the Company which imposes duties on, or involves services by, such director or executive officer with respect to the Company or any of the Company's subsidiaries, affiliates, employee benefit or welfare plans, such plan's participants or beneficiaries or any other enterprise, foreign or domestic. In the event that the Board Director shall be a director, officer, employee or agent of another corporation, partnership, joint venture, limited liability company, trust, employee benefit or welfare plan or other enterprise, foreign or domestic, 50% or more of the



ordinary shares, combined voting power or total equity interest of which is owned by the Company or any subsidiary or affiliate thereof, then it shall be presumed conclusively that the Board Director is so acting at the request of the Company.

- Indemnification. Subject to Section 6 below, the Company hereby agrees to hold harmless
 and indemnify the Board Director to the fullest extent permitted by law. In furtherance of the
 foregoing indemnification and without limiting the generality thereof:
- a. <u>In General.</u> The Company shall indemnify the Board Director if the Board Director is a party to or threatened to be made a party to or is otherwise involved in any Proceeding against all Expenses which are actually and reasonably incurred by the Board Director in connection with such a Proceeding, if the Board Director acted in good faith and in a manner the Board Director reasonably believed to be in, or not opposed to, the best interests of the Company.
- b. <u>Indemnification for Expenses of Witness</u>. Notwithstanding any other provision of this Exhibit, to the extent that the Board Director has prepared to serve or has served as a witness or is made to respond to discovery requests in any Proceeding to which the Board Director is not a party, the Board Director shall be indemnified against all Expenses actually and reasonably incurred by the Board Director in connection therewith.
- c. <u>Partial Indemnification</u>. If Board Director is entitled under any provision of this Exhibit to indemnification by the Company for some or a portion of Expenses incurred in connection with any Proceedings, but not, however, for the total amount thereof, the Company shall nevertheless indemnify Board Director for the portion of such Expenses to which Board Director is entitled.
- 3. <u>Contribution.</u> If the indemnification provided in Section 2 above is unavailable to Board Director for any reason (other than those set forth in Section 6 below) in connection with a Proceeding in which the Company is jointly liable with Board Director (or would be if joined in such Proceeding), the Company, in lieu of indemnifying Board Director thereunder, shall contribute to the amount of Expenses which are actually and reasonably incurred and paid or payable by the Board Director in such proportion as is deemed fair and reasonable by the person or persons presiding over the Proceeding in light of all of the circumstances of such Proceeding in order to reflect (i) the relative benefits received by the Company and the Board Director and/or (ii) the relative fault of the Company and such Board Director in connection with the transaction or events from which such Proceeding arose. The relative fault of the Company and the Board Director shall be determined by reference to, among other things, the parties' relative intent, knowledge, access to information and opportunity to correct or prevent the circumstances resulting in such Expenses.
- 4. Advancement of Expenses. The Expenses incurred by the Board Director in any Proceeding shall be paid promptly by the Company in advance of the final disposition of the Proceeding at the written request of the Board Director to the fullest extent permitted by applicable law; provided, however, that the Board Director shall set forth in such request reasonable evidence that such Expenses have been incurred by the Board Director in connection with such Proceeding and hereby undertakes to repay any advances if it is ultimately determined as provided in subsection 5(b) of this Exhibit that the Board Director is not entitled to indemnification under this Exhibit, the Articles, applicable law or otherwise.
 - 5. Indemnification Procedure; Determination of Right to Indemnification.
- a. Promptly after receipt by the Board Director of notice of the commencement of any Proceeding, the Board Director shall, if a claim for indemnification in respect thereof is to be made against the Company under this Exhibit, notify the Company of the commencement thereof in a written request, including therein or therewith such documentation and information as is reasonably available to Board Director and is reasonably necessary to determine whether and to what extent Board Director is entitled to indemnification. The omission to so notify the Company will not relieve the Company from any liability which the Company may have to the Board Director under this Exhibit unless the Company shall have lost significant substantive or procedural rights with respect to the defense of any Proceeding as a result of such omission to so notify.



- b. The Board Director shall be conclusively presumed to be entitled to indemnification under this Exhibit unless a determination is made that the Board Director is not entitled to indemnification under this Exhibit, the Articles, applicable law or otherwise by (i) a majority vote of the Board of a quorum consisting of Disinterested Directors or (ii) if a quorum of the Board consisting of Disinterested Directors is not obtainable, by Independent Legal Counsel in a written opinion to the Board, a copy of which shall be delivered to the Board Director. The Board Director agrees that the delivery of such opinion to the Board Director does not constitute a waiver of any privilege or doctrine, including the attorney-client privilege and the work product doctrine, with respect to any other communication between the Independent Legal Counsel and its client or clients.
- If (i) a determination is made that the Board Director is not entitled to indemnification under this Exhibit or (ii) a claim for indemnification or advancement of Expenses under this Exhibit is not paid by the Company within thirty (30) days after receipt by the Company of written notice thereof, the Board Director is entitled to an adjudication in any court of competent jurisdiction. Such judicial proceeding shall be made de novo. The burden of proving that indemnification or advances are not appropriate shall be on the Company. Neither the failure of the directors of the Company or Independent Legal Counsel to have made a determination prior to the commencement of such action that indemnification or advancement of Expenses is proper in the circumstances because the Board Director has met the applicable standard of conduct, if any, nor an actual determination by the directors of the Company or Independent Legal Counsel that the Board Director has not met the applicable standard of conduct shall be a defense to an action by the Board Director or create a presumption for the purpose of such an action that the Board Director has not met the applicable standard of conduct. The termination of any Proceeding by judgment, order, settlement or conviction, or upon a plea of nolo contendere or its equivalent, shall not, of itself (i) create a presumption that the Board Director did not act in good faith and in a manner which he reasonably believed to be in the best interests of the Company and/or its shareholders, and, with respect to any criminal Proceeding, that the Board Director had reasonable cause to believe that his conduct was unlawful or (ii) otherwise adversely affect the rights of the Board Director to indemnification or advancement of Expenses under this Exhibit, except as may be provided herein.
- d. If a court of competent jurisdiction shall determine that the Board Director is entitled to any indemnification or advancement of Expenses hereunder, the Company shall pay all Expenses actually and reasonably incurred by the Board Director in connection with such adjudication (including, but not limited to, any appellate proceedings).
- e. With respect to any Proceeding for which indemnification or advancement of Expenses is requested, the Company will be entitled to participate therein at its own expense and, except as otherwise provided below, to the extent that it may wish, the Company may assume the defense thereof, with counsel reasonably satisfactory to the Board Director. After notice from the Company to the Board Director of its election to assume the defense of a Proceeding, the Company will not be liable to the Board Director under this Exhibit for any Expenses subsequently incurred by the Board Director in connection with the defense thereof, other than as provided below.
- f. The Company shall not settle any Proceeding in any manner which would impose any penalty or limitation on the Board Director without the Board Director's written consent. The Board Director shall have the right to employ his own counsel in any Proceeding, but the fees and expenses of such counsel incurred after notice from the Company of its assumption of the defense of the Proceeding shall be at the expense of the Board Director, unless (i) the employment of counsel by the Board Director has been authorized by the Company, (ii) the Board Director shall have reasonably concluded that there may be a conflict of interest between the Company and the Board Director in the conduct of the defense of a Proceeding, or (iii) the Company shall not in fact have employed counsel to assume the defense of a proceeding, in each of which cases the fees and expenses of the Board Director's counsel shall be advanced by the Company. The Company shall not be entitled to assume the defense of any Proceeding brought by or on behalf of the Company or as to which the Board Director has reasonably concluded that there may be a conflict of interest between the Company and the Board Director.



- g. Board Director shall give the Company such information and cooperation as it may reasonably require and as shall be within Board Director's power. Subject to Section 3, the Company shall not be liable to indemnify the Board Director under this Exhibit with regard to any judicial action if the Company was not given a reasonable and timely opportunity, at its expense, to participate in the defense, conduct and/or settlement of such action.
- <u>Limitations on Indemnification</u>. Notwithstanding any provision in this Exhibit, the Company shall not be obligated under this Exhibit to make any indemnity in connection with any claim made against the Board Director:
- a. in connection with any Proceeding initiated or brought voluntarily by the Board Director and not by way of defense, unless (i) the Board authorized the Proceeding prior to its initiation or (ii) the Proceeding is to enforce indemnification rights under this Exhibit, the Articles, applicable law or otherwise and either (A) Board Director is successful in such Proceeding in establishing Board Director's right, in whole or in part, to indemnification or advancement of Expenses hereunder (in which case such indemnification or advancement shall be to the fullest extent permitted by this Exhibit) or (B) the court in such Proceeding shall determine that, despite Board Director's failure to establish his right to indemnification, Board Director is entitled to indemnity for such expenses (in which case such indemnification or advancement shall be to the extent provided by such court);
- b. in connection with the Board Director preparing to serve or serving as a witness in voluntary cooperation with any non-governmental or non-regulatory party or entity who or which has threatened or commenced any action or proceeding against the Company, or any director, officer, employee, trustee, agent, representative, subsidiary, parent corporation or affiliate of the Company, but such indemnification may be provided by the Company if the Board finds it to be appropriate;
- c. for which payment has actually been made to the Board Director under a valid and collectible insurance policy, except in respect of any excess beyond the amount of payment under such insurance policy;
- d. for an accounting of profits made from the purchase or sale by the Board Director of securities of the Company pursuant to the provisions of Section 16(b) of the Act or similar provisions of any federal, state or local statute or regulation;
- e. if a court of competent jurisdiction finally determines that such indemnification is unlawful;
- f. subject to the proviso in Section 6(a) hereof, in connection with any dispute or breach arising under any contract or similar obligation between the Company or any of its subsidiaries or affiliates and such Board Director.
- 7. Insurance. To the extent that the Company maintains an insurance policy or policies providing liability insurance for directors, officers, employees, or agents or fiduciaries of the Company or of any other corporation, partnership, joint venture, trust, employee benefit plan or other enterprise that such person serves at the request of the Company, the Board Director shall be covered by such policy or policies in accordance with its or their terms to the maximum extent of the coverage available for any director, officer, employee, agent or fiduciary under such policy or policies. If, at the time of the receipt of a notice of a Proceeding pursuant to the terms hereof, the Company has directors' and officers' insurance in effect, the Company shall give prompt notice of the commencement of such Proceeding to the insurers in accordance with the procedures set forth in the respective policies. The Company shall thereafter take all necessary or desirable action to cause such insurers to pay, on behalf of the Board Director, all amounts payable as a result of such Proceeding in accordance with the terms of such policies.
- Continuation of Indemnification. All Exhibits and obligations of the Company contained herein shall continue during the period that the Board Director is a director of the Company (or is or was serving at the request of the Company as an agent of another enterprise, foreign or domestic) and shall continue



thereafter so long as the Board Director shall be subject to any Proceeding by reason of the fact that the Board Director is or was a director of the Company or is or was serving in any other capacity referred to in this Section 8. This Exhibit shall continue in effect regardless of whether the Board Director continues to serve as a director of the Company or as an agent of another enterprise at the Company's request.

- 9. <u>Indemnification Hereunder Not Exclusive.</u> The indemnification provided by this Exhibit shall not be deemed to be exclusive of any other rights to which the Board Director may be entitled under the Articles, Director Appointment Letter, any Exhibit, vote of shareholders or vote of Disinterested Directors, provisions of applicable law, or otherwise, both as to action or omission in the Board Director's official capacity and as to action or omission in another capacity on behalf of the Company while holding such office.
- 10. Exhibit To Serve. The Company acknowledges that it has entered into this Exhibit and assumes the obligations imposed on it hereby, in addition to and separate from its obligations to Board Director under the Articles, Director Appointment Letter or otherwise to induce Board Director to serve, or continue to serve, as a director of the Company, and the Company acknowledges that Board Director is relying upon this Exhibit in serving as a director of the Company.
- Interpretation of Exhibit. It is understood that the parties hereto intend this Exhibit to be interpreted and enforced so as to provide indemnification to Board Director to the fullest extent now or hereafter permitted by law.
- 12. <u>Subrogation</u>. In the event of payment under this Exhibit, the Company shall be subrogated to the extent of such payment to all of the rights of recovery of the Board Director, who shall execute all documents required and shall do all acts that may be necessary to secure such rights and to enable the Company effectively to bring suit to enforce such rights separate and distinct so that if any section, sentence, term or provision thereof shall be held to be invalid, unlawful or unenforceable for any reason, such invalidity, unlawfulness or unenforceability shall not affect the validity, lawfulness or enforceability of any other section, sentence, term or provision hereof.
- 13. <u>Savings Clause.</u> If this Exhibit or any section, sentence, term or provision hereof is invalidated on any ground by any court of competent jurisdiction, the Company shall nevertheless indemnify the Board Director as to any Expenses which are incurred with respect to any Proceeding to the fullest extent permitted by any (a) applicable section, sentence, term or provision of this Exhibit that has not been invalidated or (b) applicable law. To the extent required, any section, sentence, term or provision of this Exhibit may be modified by a court of competent jurisdiction to preserve its validity and to provide the Board Director with the broadest possible indemnification permitted under applicable law.



Board Member Agreement

This Agreement (this "Agreement"), dated as of the 20th day of March 2018, is between, <u>Donald H. MacAdam</u>, an individual having a residence at 56 Kelly Drive, Port Dover, Ontario, Canada N0A 1N5, (the "Board Director"), and XBiotech Inc., a Canadian corporation with a place of business at 300-1055 West Hastings Street, Vancouver BC V6E 2E9 Canada (the "Company").

WHEREAS, the parties desire to enter into this Agreement setting forth the terms and conditions of the Board Director with the Company;

NOW, THEREFORE, the parties agree as follows:

- Effective Date. This Agreement shall be effective as of the 19th day of March 2018 (the "Effective Date").
- Term. Subject to the provisions of Section 13 of this Agreement, this Agreement shall commence on the Effective Date and be effective until the date terminated by either the Company or Board Director (the "Term").
- Position. During the Term, the Board Director shall act as a "Board Member" to the Company.
- 4. <u>Duties and Reporting Relationship.</u> During the Term, the Board Director shall be generally available for mutually agreed times during business hours. The Board Director agrees that they shall represent the Company as a "Board Member". Such representations may be made by the Company in SEC filings, during Presentations, Business Plans, on the Company Website, or any other place deemed fit by the Company. The Company may request that you participate in discussions, as suitable to your schedule and availability, with third parties from time to time. You will be asked to chair the Company's compensation committee.
- 5. Compensation: On the effective date of this agreement, Donald H. MacAdam (the "Option Holder") will be granted non-qualified stock options under the Company's 2015 Equity Incentive Plan (the "Plan") to purchase 25,000 shares of the Company's common stock, and an additional 12,500 options will be granted on or about the date of the Company's annual stockholders meeting. During Option Holder's service as a Board Member in years following 2018, the Option Holder will be granted 25,000 options annually on or about the date of the Company's annual stockholders meeting. All granted options will be exercisable at a price equal to the closing price of the Company's common stock, as reported by NASDAQ, on the date of grant, and vest in two equal installments occurring six months and 12 months following the date of grant, subject to continued service as a Director (the "Options"). The Options shall expire ten years from the date of grant, unless terminated earlier in accordance with the Plan or the Option Holder's stock option agreement. In accordance with the Plan or the Option Holder's resignation.
- 6. Engagement: The Board Director will be compensated for services provided by telephone, in person meetings, time spent on written work, as well as time spent traveling to or from meetings/events. Performance of these duties requires that the Board Director is formally requested to provide these services. A formal request is preferably in the format of a written document/email, but may also include verbal requests that have been clearly discussed between both parties.
- 7. <u>Business Expense</u>. The Board Director shall be reimbursed for all ordinary and necessary business expenses incurred by the Board Director in connection with her agreement upon timely submission to the Company of receipts and other documentation as required by the Internal Revenue Code of 1986, as amended, and in conformance with the Company's normal expense reimbursement policies and



- procedures. Executive shall be entitled to reimbursement at first class commercial airline rates for transcontinental travel.
- Indemnification and Insurance. Exhibit A hereto, which is hereby incorporated herein as if set forth herein, sets forth certain agreements of the parties hereto in respect of indemnification and insurance.
- 9. Termination of the Agreement. The Board Director or the Company may terminate this agreement at any time for any reason. The Agreement hereunder shall automatically terminate upon the death of the Board Director. Any purported termination of the Board Director's agreement by the Company or by the Board Director shall be communicated by written notice of termination to the other party hereto.

10. Representation and Warranties.

- a. The Company represents and warrants that this Agreement has been authorized by the Company and is a valid and binding agreement of the Company enforceable against it in accordance with its terms.
- b. The Board Director represents and warrants that he is not a party to any agreement or instrument which would prevent him from entering into or performing his duties under this Agreement.
- 11. Confidentiality. The Board Director agrees to be subject to the Company's reasonable policies concerning Confidentiality and Non-Disclosure as in effect from time to time. The Company agrees that nothing herein or therein shall prevent the Board Director from rendering services in any capacity to any other person or business from time to time, subject to the compliance with any confidentiality and non-disclosure obligations, to the Board Director's obligations as a fiduciary of the Company and to applicable law.

12. Successors; Binding Agreement.

- a. This Agreement shall not be assignable by the Board Director.
- b. This Agreement is a personal contract and the rights and interests of the Board Director hereunder may not be sold, transferred, assigned, pledged, encumbered, or hypothecated by him, except as otherwise expressly permitted by the provisions of this Agreement. This Agreement shall inure to the benefit of and be enforceable by the Board Director and her personal or legal representatives, executors, administrators, successors, heirs, distributes, devisees and legatees. If the Board Director should die while any amount would still be payable to her hereunder had the Board Director continued to live, all such amounts, unless otherwise provided herein, shall be paid in accordance with the terms of this Agreement to her devisee, legatee or other designee or, if there is no such designee, to her estate.
- c. The obligations of the Company hereunder may not be assigned by the Company without the prior written consent of the Board Director. This Agreement shall be binding upon and be enforceable against the Company's successors (including any direct or indirect successor by purchase, merger, consolidation, or otherwise to all or substantially all of the business and/or assets of the Company) and assigns, as well as the Board Director's spouses, heirs, and personal and legal representatives.
- 13. Entire Agreement. This Agreement contains all the understandings between the parties hereto pertaining to the matters referred to herein, and on the Effective Date shall supersede all undertakings and agreements, whether oral or in writing, previously entered into by them with respect hereto. The Board Director represents that, in executing this



Agreement, he does not rely and has not relied upon any representation or statement not set forth herein made by the Company with regard to the subject matter, bases or effect of this Agreement or otherwise.

- 14. Amendment or Modification; Waiver. No provision of this Agreement may be amended or waived unless such amendment or waiver is agreed to in writing, signed by the Board Director and by a duly authorized officer of the Company. No waiver by any party hereto of any breach by another party hereto of any condition or provision of this Agreement to be performed by such other party shall be deemed a waiver of a similar or dissimilar condition or provision at the same time, any prior time or any subsequent time.
- 15. Notices. Any notice to be given hereunder shall be in writing and shall be deemed given when delivered personally, sent by courier or telecopy or registered or certified mail, postage prepaid, return receipt requested, addressed to the party concerned at the address indicated below or to such other address as such party may subsequently give notice of hereunder in writing:

To the Board Director at:

To the Company at:

Attention: John Simard, President & CEO XBiotech USA, Inc. 8201 E Riverside Dr. Bldg. 4 Ste. 100 Austin, TX 78744

Any Notice delivered personally or by courier under this Section 12 shall be deemed given on the date delivered and any notice sent by telecopy or registered or certified mail, postage paid, return receipt requested, shall be deemed given on the date telecopied or mailed.

- 16. Severability. If any provision of this Agreement or the application of any such provision to any party or circumstances shall be determined by any court of competent jurisdiction to be invalid and unenforceable to any extent, the remainder of this Agreement or the application of such provision to such person or circumstances other than those to which it is so determined to be invalid and unenforceable, shall not be affected thereby, and each provision hereof shall be validated and shall be enforced to the fullest extent permitted by law.
- Survivorship. The respective rights and obligations of the parties hereunder shall survive any termination of this Agreement to the extent necessary to the intended preservation of such rights and obligations.
- 18. Governing Law and Jurisdiction. This Agreement will be governed by and construed in accordance with the laws of the State of Delaware, without regard to its conflicts of the laws principles. Each of the parties to this Agreement agrees that the courts of the States of Delaware and New York shall have exclusive jurisdiction to hear and determine any claim, suit, action or proceeding, and to settle any disputes, which may arise out of or are in any way related to or in connection with this Agreement.
- Headings. All descriptive headings of the sections and paragraphs in this Agreement are intended solely for convenience, and no provision of this Agreement is to be construed by reference to the heading of any section or paragraph
- 20. <u>Taxes</u>. The parties agree to cooperate in respect of tax withholding and reporting consequences of the arrangements described herein. The parties acknowledge that there is no U.S. federal tax withholding requirement applicable under current law to the compensation described herein. The Company agrees to facilitate, to the extent



reasonably practical, the performance of the Board Director's services in a manner that minimizes the Board Director's U.S. tax obligations.

21. <u>Counterparts.</u> This Agreement may be executed and delivered, including by facsimile transmission or by electronic transmission in Adobe portable document format (or a "<u>PDF file</u>"), in counterparts, each of which shall be deemed an original, and all of which taken together shall constitute one and the same instrument.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the date first above written.

Donald H. MacAdam

John Simard President & CEO

LIST OF SUBSIDIARIES

Name Country

XBiotech USA, Inc.

United States

(Delaware)

XBiotech Germany GmbH Germany

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, 2023 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, 2022.

/s/ Whitley Penn LLP Austin, Texas March 15, 2023

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the following Registration Statements:

- 1. Registration Statement (Form S-8 No. 333-207476) pertaining to the 2005 Incentive Stock Option Plan and 2015 Equity Incentive Plan of XBiotech Inc.; and
- 2. Registration Statement (Form S-8 No. 333-249288) pertaining to the 2015 Equity Incentive Plan of XBiotech Inc.

of our report dated March 15, 2022, with respect to the consolidated financial statements of XBiotech Inc. included in this Annual Report (Form 10-K) of XBiotech Inc. for the year ended December 31, 2021.

/s/ Ernst & Young LLP Austin, Texas March 15, 2022

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, 2023

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

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, 2023

/s/Angela Hu Angela Hu

Principal Financial Officer and Principal Accounting Officer

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, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, John Simard, Chief Executive Officer and President of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of XBiotech Inc.

/s/JOHN SIMARD

John Simard Chief Executive Officer and President (Principal Executive Officer) Date: March 15, 2023

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, 2022 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

Principal Financial Officer and Principal Accounting Officer

Date: March 15, 2023