XBiotech Inc.
Form 10-K
March 30, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2015

Commission file number 001-37437

XBIOTECH INC.

(Exact name of Registrant as specified in its charter)

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

8201 E. Riverside Drive, Bldg. 4, Suite 100

Austin TX 78744

(Address of principal executive offices, including zip code)

Telephone Number (512) 386-2900

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Name of each exchange on which registered**
Common Stock, par value $0.0001 per share	NASDAQ Global 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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant’s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of “large accelerated filer,” “accelerated filer” and “smaller reporting company” in Rule 12b-2 of the

Exchange Act.

Large accelerated filer Accelerated filer Non-accelerated filer Smaller Reporting Company

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of June 30, 2015, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $348,728,794, 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 12,752,867 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 30, 2016, 32,292,106 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 2016 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 contain forward-looking statements that involve substantial risks and uncertainties. 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.

These forward-looking statements include declarations regarding our management's beliefs and current expectations. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "would," "could," "expects," "plans," "contemplate," "anticipates," "believes," "estimates," "predicts," "projects," "intend" or "continue" or the negative of such terms or other comparable terminology, 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, 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 Xilonix™ 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 Xilonix™ and other product candidates;*
- *our ability to advance product candidates into, and successfully complete, clinical trials;*
- *our ability to successfully commercialize the sale of Xilonix™ 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;*
- *our ability to obtain funding for our operations, including research funding;*
- *our ability to identify additional new products using our True Human™ antibody discovery platform;*
- *the implementation of our business model and strategic plans;*

- *our ability to develop and commercialize product candidates for orphan and niche indications independently;*

- *our commercialization, marketing and manufacturing capabilities and strategy;*

- *our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others;*

- *our expectations regarding federal, state and foreign regulatory requirements;*

- *the therapeutic benefits, effectiveness and safety of our product candidates;*

- *the accuracy of our estimates of the size and characteristics of the markets that may be addressed by our products and product candidates;*
- *the rate and degree of market acceptance and clinical utility of Xilonix™ and future products, if any;*
- *the timing of and our collaborators' ability to obtain and maintain regulatory approvals for our product candidates;*
- *our expectations regarding market risk, including interest rate changes and foreign currency fluctuations;*
- *our belief in the sufficiency of our cash flows to meet our needs for at least the next 12 to 24 months;*
- *our expectations regarding the timing during which we will be an emerging growth company under the JOBS Act;*
- *our ability to engage and retain the employees required to grow our business;*
- *our future financial performance and projected expenditures;*
- *developments relating to our competitors and our industry, including the success of competing therapies that are or become available; and*
- *estimates of our expenses, future revenue, capital requirements and our needs for additional financing.*

You should also read the matters described in the "Risk Factors" and the other cautionary statements made in this annual report 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.

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PART I

ITEM 1 BUSINESS

Overview

XBiotech is a clinical-stage 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. While focused on bringing our lead product candidate to market, we also have developed a True Human™ pipeline and manufacturing system.

The majority of our efforts to date have been concentrated on developing MABp1 (also known as Xilonix™, CA-18C3, CV-18C3, RA-18C3, and T2-18C3), a therapeutic antibody which specifically neutralizes interleukin-1 alpha (IL-1a). IL-1a is a pro-inflammatory protein produced by leukocytes and other cells, where it plays a key role in inflammation. When unchecked, inflammation can contribute to the development and progression of a variety of different diseases such as cancer, vascular disease, inflammatory skin disease, and diabetes. Our clinical studies have shown that blocking IL-1a with MABp1 may have a beneficial effect in several diseases.

We completed a Phase I and II clinical trial for MABp1 as a treatment for cancer at MD Anderson Cancer Center. The results of this study, published in Lancet Oncology in April 2014, found that in the 52 patients with metastatic cancer (18 tumor types) who participated, MABp1 was well tolerated, with no dose-limiting toxicities or immunogenicity. Moreover, within eight weeks of starting therapy many patients began to improve with respect to constitutional symptoms. An imaging method, known as dual energy X-ray absorptiometry (DEXA), revealed that many of the patients improved physically, in terms of gaining lean body mass; and patient reported outcomes documented that many were recovering from pain, fatigue and appetite loss. Finally, we found that in the patients with colorectal cancer, DEXA-measured recovery was associated with significant improvement in survival.

We received a fast track designation from the FDA in October 2012 to develop Xilonix™ as a treatment in the setting of metastatic colorectal cancer. The purpose of the fast track designation is to aid in the development, and expedite the review, of drugs that have the potential to treat a serious or life-threatening disease. Currently one Phase III study is underway in the United States for advanced refractory colorectal cancer. We recently completed another Phase III study in Europe for symptomatic colorectal cancer at the end of 2015. With the success of the European Phase III trial, we are now in the process of seeking marketing approval for MABp1 at the European Medicines Agency. If the United States Phase III trial is also successful, we will seek marketing approval for MABp1 at the U.S. Food and Drug Administration. Assuming such marketing approvals are obtained, we would distribute and sell this product through our own direct sales force or with a commercial partner.

We are also investigating MABp1 in clinical trials for other indications including vascular disease, type II diabetes, acne and psoriasis. In a randomized Phase II study involving 43 patients, we evaluated MABp1 for its ability to reduce adverse events after balloon angioplasty, atherectomy or stent placement in patients undergoing revascularization procedures for blockage of the superficial femoral artery (SFA), a major artery in the leg. While the study did not involve a large enough patient population to provide a statistically significant outcome, results from this study showed an important trend towards the reduction of restenosis and reduced incidence of Major Adverse Cardiovascular Events (MACE) in treated patients compared to the control group. In 2012, we obtained a fast track designation to develop MABp1 as a therapy to reduce the need for re-intervention after treatment of peripheral vascular disease with

angioplasty or other endovascular methods of treatment. We have also entered into an agreement with Dr. Peter Libby, to examine the effects of IL-1a blockade in mouse models of acute myocardial infarction and atherosclerosis.

In a Phase II pilot study completed in 2012, we tested MABp1 in patients with type II diabetes. A treatment-related decline in HbA1c, and increased serum levels of pro-insulin and C-peptide (indicators of improved glucose control and pancreas function, respectively) were observed. We also conducted two Phase II pilot studies in skin disease, evaluating the potential benefit of MABp1 in subjects with (1) moderate to severe plaque psoriasis and (2) moderate to severe acne vulgaris. The psoriasis study revealed rapid improvements in the Psoriasis Area and Severity Index (PASI), with patients having a median of 43% improvement within 35 days. In the acne study, treated patients exhibited a continual improvement in lesions over the course of therapy, with up to 42% reduction in eight weeks; and interestingly, these patients had a statistically significant improvement in anxiety, as measured by the Hospital Anxiety and Depression Scale (HADS). We continue to analyze our clinical results, and prioritize further clinical initiatives for MABp1 in oncology, SFA, diabetes, psoriasis and acne.

We recently filed an Investigational New Drug Application (IND) for a True Human™ Antibody therapy we are developing to treat infections due to Staphylococcus aureus. This product candidate was identified from an individual that harbored a natural antibody capable of neutralizing drug-resistant strains of Staphylococcus aureus. This agent is currently progressing through a Phase I and II study, after being released from clinical hold last year. The hold was implemented by the FDA so that an animal toxicology study could be performed prior to dosing patients in clinical trials.

In February 2015, we received a blood donation from an Ebola-recovered patient, which was confirmed to have high levels of anti-Ebola antibodies. We signed an agreement with the US Army Medical Research Institute for Infectious Diseases (USAMRIID) to test these antibodies, and by October 2015, their results showed that 8 out of our 10 antibodies candidates were able to neutralize the deadly Ebola virus using in vitro assays. In addition, we received the blood donations from two patients that had each recently recovered from Ebola infection through our contractual relationship with the South Texas Blood & Tissue Center, a 501(c) not for profit organization (STBTC), and have an obligation to pay STBTC a low single-digit royalty payment on any Ebola product that we develop based on these donations,

More recently, we have begun using our True Human™ antibody technology to develop a therapy against clostridium difficile. Clostridium difficile (C. diff) is a bacterium that can cause severe infections in the gastrointestinal tract. The infection is greatest for individuals who are being treated with antibiotics, those that are hospitalized or in nursing homes, and the elderly. Additionally, about 1 in 5 patients that become infected with C. diff experience a relapse and need to be re-treated. Over the past decade, C. diff has emerged as a significant public health threat, and we feel that it is a serious and unmet need for patients worldwide. In fact, the colorectal cancer (CRC) has designated it as an “Urgent threat level”, meaning that it is an immediate public health threat that requires urgent and aggressive action.

Our True Human™ antibody therapeutics are developed in-house using our proprietary discovery platform. Identifying True Human™ antibodies useful for therapeutics may involve screening thousands of blood donors. To distinguish the clinically relevant antibodies from irrelevant background antibody molecules in donor bloods, we use our Super High Stringency Antibody Mining (SHSAM™) technology. After we identify donors, we undertake a complex process identifying the responsible genes for producing the native antibody. Once the nucleic acid sequence is isolated, we are able to clone these genes into production cells to manufacture large quantities of product candidate for use in humans. All patents and other intellectual property relating to both the composition of matter and methods of use of our True Human™ antibodies were developed internally by us. We manufacture these antibodies using a proprietary expression system licensed from Lonza Sales AG. The manufacturing process we have developed incorporates both proprietary and non-proprietary technology.

A key aspect of our manufacturing system involves the use of simple disposable bioreactor technology. Our manufacturing operation is currently located within our forty-six thousand square foot facility in Austin, Texas. To accommodate larger-scale commercial manufacturing needs, we purchased 48 acres of industrial-zoned property located five miles from Austin’s central business district. In September 2014, we commenced ground-breaking on a new manufacturing facility on this property. Construction is estimated to be completed by mid 2016, with an anticipated operation date in mid 2016.

A Background on Therapeutic Antibodies

A century ago scientists and physicians envisioned being able to custom design therapeutic agents that were highly specific for a single biological target. By selectively attacking disease while sparing healthy tissue, these “magic bullets” were thought 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 have been 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 potentially damaging 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 selectively attach to and neutralize different disease targets. The vast array of possible treatments based on antibodies lead to the development of what is now a major industry around the use of therapeutic antibodies.

True Human™ 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 Human™ 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 Human™ 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 Human™ 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™ 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 the circulation. The vast number of different antibodies (and cells that produce them), are essential to enable adequate molecular diversity to ward off all 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 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 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 Human™ antibodies manufactured using recombinant protein technology currently marketed. If successful in clinical development, our lead product Xilonix™ is expected to be the first True Human™ therapeutic antibody to be commercialized.

Platform Technology

There are significant technical challenges in identifying and cloning genes for True Human™ antibodies. A key problem to overcome can be to first identify individuals with the desired antibody reactivity. This can involve screening hundreds of 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. We screen human donors to find an individual who has in his or her blood a specific antibody that we believe will be protective against a certain disease. White blood cells from that individual can then be isolated, and the unique gene that produced the 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. See "Intellectual Property- Other Commercial Licenses."

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 Human™ antibody for use in clinical therapy. A True Human™ 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 oncology, diabetes, dermatology and infectious disease indications. At present, our therapy for colorectal cancer, in which we have completed one Phase III study and have another ongoing, is the most advanced.

Cancer Business and the Market for Colorectal Therapies

The development of new therapies for the treatment of cancer continues to be a fundamental area of focus and growth in the pharmaceutical and biopharmaceutical industry. Detailed and thorough analysis of the oncology business, including that for colorectal cancer, is available from a number of research specialists. In brief, over the past decade expenditures in R&D and revenues derived from oncology related sales have continued to grow largely as anticipated. According to the independent research group IMS Health, the market for cancer drugs grew at an annual rate of about 5% between 2008 and 2013, which is slower than previous years, but still makes it by far the largest sector of the pharmaceutical industry. In 2017, they predict between $74 and $84 billion in sales, double that of the second place

area of sales, which is diabetes.

The three major regional markets for cancer drugs are the United States, Europe and Japan, with US sales representing about 40% of the global market share. The largest revenue earners in the oncology space are the therapeutic antibodies Avastin, Herceptin and Rituximab, with combined sales reported to be over $20 billion in 2013.

The market for colorectal cancer (CRC) drugs is expected to grow, according to the independent research group RnRMarketResearch.com, at a compound annual growth rate of 1.8%, to reach $9.4 billion in annual sales over the next 5 years. The US market for CRC therapeutics commands about 44% of the global business, more than double that of the next biggest market, Japan.

According to RnRMarketResearch.com, however, growth for the CRC drug business is expected to be tempered by increasing availability of biosimilar competitors, particularly those challenging leading products such as Avastin and Herceptin. There is also a substantial pipeline for CRC therapeutics across the industry in various stages of commercialization that are expected to bring new drugs to patients and competition to the market place.

An intense industry focus on developing new therapies for CRC is not surprising since this a highly prevalent form of cancer. According to the American Cancer Society, Surveillance Research 2015, nearly 130,000 men and women in the United States will be diagnosed with CRC in 2015. This represents almost 20% of all forms of cancer that will be diagnosed in 2015. In terms of mortality, as many as 50,000 people are expected to die from the disease in 2015 and many more will be refractory to existing therapy.

Our therapeutic antibody Xilonix™ is being evaluated as a monotherapy to treat advanced stages of colorectal cancer. If Xilonix™ therapy proves successful in both its Phase III clinical programs, it will have demonstrated the ability to not only increase survival of patients, but also to facilitate recovery and reduce debilitating symptoms of the disease.

We are aware of no other cancer therapy either marketed or in development that achieves overall survival benefit and in the course of treatment improves quality of life, and facilitates physical recovery of advanced cancer patients. While the market for CRC drugs is competitive and dynamic, in the event marketing approval is established for Xilonix™, we expect this therapy to be a highly valued and unique therapy in oncology, providing for significant market share in advanced CRC.

Our Strategy

Our objective is to fundamentally change the way therapeutic antibodies are developed and commercialized, and become a leading biopharmaceutical company focused on the discovery, development and commercialization of therapeutic True Human™ antibodies. The key goals of our business strategy are to:

- Obtain regulatory approval to market and sell Xilonix™ in the United States, Europe and other markets, and begin commercial sale of Xilonix™;
- Continue our research and clinical work on infectious diseases, including S. *aureus*;
- Review our clinical results for SFA, diabetes, psoriasis and acne and determine additional research or clinical studies, which we may conduct in the future;
- Discover other True Human™ antibody therapies using our proprietary platform; and
- Leverage our manufacturing technology.

Product Pipeline

Our product development status for the fourth quarter of 2015 was as follows:

Competition

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. While there are numerous independent reviews on the subject in both trade journals and academic press, XBiotech has analyzed and attempted to synthesize these publicly available data in order to understand, at least at the broadest level, the competitive landscape for its products.

While we believe True Human™ therapeutic antibodies are an important positive differentiating factor from other monoclonal antibodies currently marketed, we also believe the unique activity of our anti-cancer therapeutic Xilonix™, which is being tested for its ability to both improve well beings and extend life. If proven in our Phase III clinical programs, we feel Xilonix™ will be highly differentiated in the market place for colorectal cancer therapeutics. However, regardless of the potential advantages or uniqueness of Xilonix™ 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.

As reported in the National Review of Drug Discovery (October 2010), more than 140 “fully human” antibodies had entered clinical studies and from 2004-2013 nineteen antibody therapeutics were approved in the US for marketing, with some antibodies receiving marketing approval in multiple indications (Reichert JM, Antibodies to Watch in 2014. mAbs. 6:4, 799-802). Thus the competitive landscape is both broad and complex (See below Table).

Drug	Company	Generic Name	Status of Drug	Indication
Cancer Treatments				
Yervoy ®	Bristol-Myers Squibb	Ipilmumab	FDA Approved	Melanoma
Vectibix ®	Amgen	Panitumumab	FDA Approved	Colorectal Cancer
Arzerra®	GlaxoSmithKline	Ofatumumab	FDA Approved	Leukemia
Cyramza™	Lilly	Ramucirumab	FDA Approved	Non Small-Cell Lung Cancer
Opdivo™	Bristol-Myers Squibb	Nivolumab	FDA Approved	Melanoma
Cyramza™	Lilly	Ramucirumab	FDA Approved	Gastric and Colorectal Cancer
Sylvant®	Janssen	Siltuximab	FDA Approved	Myeloma (Multicentric Castleman’s Disease)
Entyvio®	Takeda Pharmaceuticals	Vedolizumab	FDA Approved	Ulcerative Colitis and Crohn’s disease
Daratumumab	Janssen	Daratumumab	FDA Approved	Multiple Myeloma
Necitumumab	Eli Lilly	Necitumumab	FDA Approved	Non Small-Cell Lung Cancer
Patritumab	Daiichi Sanko	Patritumab	Phase III	Non Small-Cell Lung Cancer; Head and Neck Cancer
MEDI-4736	AstraZeneca	MEDI-4736	Phase III	Non Small-Cell Lung Cancer
RG7446	Roche/Genentech	RG7446	Phase III	Non Small-Cell Lung Cancer
Cardiovascular Disease Treatments	Novartis	Canakinumab	Phase III	Recurrent CV events
Pyoderma Gangrenosum Treatments	Xoma/Servier	Gevokizumab	Phase III	PG
Acne or Psoriasis Treatments				
Secukinumab	Novartis		FDA Approved	Psoriasis
Brodalumab	Amgen		Phase III	Psoriasis
Guselkumab	Janssen		Phase III	Psoriasis

Recent Developments

In 2015 the immune stimulating antibodies, pembrolizumab and nivolumab, received additional approvals thus expanding their labels melanoma into additional tumor types. Both pembrolizumab and nivolumab were approved for the treatment of NSCLC after the failure of a platinum based regimen. Nivolumab was also approved for patients with advanced renal cell carcinoma after failure of prior anti-angiogenic therapy, as well as in combination with ipilimumab in patients with metastatic or unresectable melanoma. Pembrolizumab’s melanoma label was also expanded to now include first line treatment.

Pembrolizumab and nivolumab are anticancer agents that work by activating the immune system, such that it may stimulate an immune-mediated anti-tumor cytotoxicity. There are a number of antibodies that are in development for, or have reached the oncology market, such as ipilimumab, based on this general mechanism of action. While approvals have been forthcoming with these therapies, these agents share in common severe side effects without achieving high rates of durable remission. In advanced malignant disease, these agents have and will likely continue to achieve success in the market place. Both pembrolizumab and ipilimumab are approved for the treatment of melanoma, a disease for which we currently have no clinical development plans for Xilonix™. However, with respect to the overall competitiveness of these approaches vis-à-vis Xilonix™, our Phase III clinical programs are intended to demonstrate overall survival benefit that is generally consistent with those observed with cytotoxic therapies in refractory disease. Additionally, in the case of Xilonix™, we are also attempting to demonstrate improved life quality and physical recovery. We expect that Xilonix™ will therefore compete favorably with this new and emerging class of anti-cancer antibodies.

Current Clinical Investigation Activity

European Registration Study Oncology

In the fourth quarter of 2015, we completed a double-blinded, placebo-controlled Phase III registration study in Europe. Clinical sites were located in a number of different EU member states, in addition to Russia. The study evaluated MABp1, or Xilonix™, as an anticancer therapy in patients with symptomatic colorectal cancer.

The primary objective of this study was to assess the efficacy of Xilonix™ in reversing symptoms in patients with symptomatic colorectal cancer. By blocking Interleukin-1 alpha, a cytokine involved in the growth and spread of tumors as well as a mediator of cancer associated symptoms, Xilonix™ therapy showed a statistically significant improvement in an objective response criteria as compared with placebo. This response criteria, which was developed and approved as part of the EMA Scientific Advice Procedure, evaluated a novel co-primary endpoint designed to assess clinical benefit in advanced mCRC by reversing symptoms as part of an anti-neoplastic effect.

The population studied consisted of patients with mCRC and tumor associated symptoms at baseline. Tumor related symptoms were chosen that are reliably measurable and indicative of disease progression. Moreover, symptoms were identified that, in the event of improvement, would also likely predict survival benefit for patients. For the purpose of inclusion criteria, tumor related symptoms were classified in two categories: metabolic and functional. To meet the criteria of the metabolic domain of symptoms, patients were required to have either:

1. Any degree of weight loss in the previous 6 months, which is known to predict shortened survival or;
2. A serum Interleukin-6 level ≥10 pg/ml. Elevated IL-6 levels, while widely used as a marker of systemic inflammation, have also been shown to correlate with shortened survival in many tumor types.

The EORTC QLQ-C30 is a validated quality of life instrument for assessment of cancer related symptoms. This instrument has been used in numerous oncology studies, and large meta-analyses examining patient responses have shown that a higher degree of symptoms predicts a shortened survival across all tumor types[5]. Symptom related criteria defined as functional, while quantitated with a highly reliable and validated instrument, the EORTC QLQ-C30, are entirely self-reported.

Patients included in the study were required to have evidence of one objective symptom from the metabolic domain, and one self-reported symptom from the functional domain. In addition, only those patients with performance status of 1 or 2, as measured by the Eastern Cooperative Oncology Group (ECOG) scale, were eligible for entry. Together, these inclusion criteria selected for a uniquely advanced and frail population.

For the co-primary endpoints, patients were assessed for stabilization or improvements in lean body mass, as measured by DEXA, combined with an assessment of patient well-being with respect to pain, fatigue and/or appetite loss. Specifically, stabilization or a gain in lean body mass at the 8-week follow up combined with improvement or no worsening in two of the latter measures of patient well-being, as measured by the validated EORTC QLQ-C30 questionnaire. To be considered a responder for the primary endpoint, a patient needs to meet both response criteria.

The study started in July 2014, completed in November 2015, and enrolled a total of 333 patients. The data cleaning, conducted shortly after the completion of the study, showed that fewer than expected patients were available for data analysis. We presented a short overview of these findings in a press release on November 23, 2015. As per the prospective analysis plan, the data from 24 patients was excluded from final analysis of the data as they discontinued study prior to receiving a single dose of either Xilonix™ or placebo. Because the study endpoints were satisfactorily achieved, we proceeded to submit a Marketing Authorization Application package to the European Medicines Agency (EMA) on March 7.

US Registration Study Oncology

A Phase III randomized study using Xilonix™ was started in March 2013 (IND #114,759). The study, which was recruiting patients at over sixty cancer centers in the United States was halted by us in September 2014 to propose changes in inclusion criteria to the FDA to enable faster patient recruitment. Amendments were proposed and agreed to by the FDA in order to correct what we believed to be unnecessary enrollment barriers.

Changes to the study protocol included eliminating the 5% weight loss requirement for patients and terminating the use of megesterol acetate (megace) in the control arm. The new agreed upon protocol will enable recruitment of all advanced, refractory colorectal patients regardless of weight loss, and use a 2:1 double-blinded randomization against placebo rather than a 1:1 randomization against megace. Treatment of patients under the new protocol commenced in April 2015. Enrollment under the revised protocol is expected to be completed in the second half of 2016.

Phase II study Pyoderma Gangrenosum (PG)

A phase II open-label exploratory study is underway to evaluate MABp1 for treatment of the rare skin disorder PG (IND # 112,459). PG is a chronic condition characterized by inflamed, non-healing skin ulcerations. The study is evaluating safety and efficacy of the therapy to facilitate wound healing and is being conducted at 5 sites in the United States. Primary endpoints of study involve clinicians' and patients' global assessment at day 28 from baseline. Patients who are found to be responding to therapy, but who have not yet experienced complete resolution of their lesion(s) after 28 days of therapy may participate in up to 3 additional 28-day cycles. Up to 10 patients will be enrolled on this trial, and enrollment is expected to be complete in the first half of 2016.

Phase I and II Study for Staphylococcus Aureus

We filed an Investigational New Drug Application (IND) for a Phase I and II randomized clinical study to assess our True Human™ Antibody therapy for the treatment of serious infections due to Staphylococcus *aureus.* This product candidate was identified from an individual that harbored a natural antibody capable of neutralizing S. *aureus,* including drug-resistant strains of the bacteria. The study is currently progressing through Phase I and II after being on clinical hold, at the request of the FDA, as we completed an animal toxicology study. The animal study was completed in the first quarter of 2015. The Phase I, dose escalation, portion of the study began in July 2015. The Phase II portion of the study is expected to be completed in 2016.

Non-Small-Cell Lung Cancer (NSCLC)

We entered into a Letter of Agreement at the end of 2015 with the National Cancer Institute of Canada Clinical Trials Group to develop and help facilitate a Phase II study to assess Xilonix™ in combination with Tarceva for the treatment of NSCLC. The protocol is still under development, and is expected to launch in Canada and begin enrollment in Q2 2016. This study is a follow up to the Phase I study enrolling all comers in a solid tumor study at MD Anderson Cancer Center in Houston, Texas. In particular, the data collected from a subgroup of NSCLC patients were published in *Investigational New Drugs* in March 2015. These results highlighted the potential for combination therapy in NSCLC patients treated with EGFR inhibitors. In the MD Anderson study NSCLC patients had metastatic, refractory disease at baseline and were treated with Xilonix™ monotherapy until disease progression. Patients that received prior treatment with Tarceva appeared to have considerably better outcomes than those that had not received Tarceva. In the study, radiographic evidence of tumor response, changes in lean body mass and quality of life were assessed and patients were followed for 24 months for survival analysis. Furthermore, stratification by prior therapies revealed a median overall survival for patients treated with anti-EGFR therapy of 9.4 months compared to only 4.8 months for non-pretreated patients.

Cardiovascular Disease

In the first quarter of 2016, we announced a Material Transfer Agreement (MTA) with Brigham and Women's Hospital and Massachusetts General Hospital. XBiotech will provide Antibodies to block the inflammatory mediator interleukin 1 alpha while Novartis Pharmaceuticals will provide an interleukin 1 beta antibody to a research team headed by cardiovascular medicine specialist Dr. Peter Libby. The research team will conduct pre-clinical studies to assess the potential of these antibodies to reduce injury to the heart muscle after heart attack, as well as comparing the treatment effects of these antibodies on inflammation in atherosclerotic plaques.

Summary of Clinical Findings to Date

Safety

Our lead product under development, MABp1, is derived from a natural human immune response. We expected that this would 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. We believe that these reactions are the result of using antibodies that were not derived from natural human immunity but rather had engineered specificities. Based on scientific principles of antibody physiology, a fundamentally important premise was that our True Human™ antibody therapy should be safer and result in less infusion-related complications than engineered human antibodies when used in clinical studies.

As illustrated in the table below, therapeutic monoclonal antibodies, even those so-called "fully human," have been associated with infusion reactions (see table below). Over 2000 doses of MABp1 have been administered to more than 300 patients in nine different clinical trials. As of March 3, 2016, there have been 2 infusion reactions with MABp1.

Reports of Infusions Reactions from Leading marketed "Fully Human" Antibody Products Versus MABp1 (Table below).

Fully Human Antibodies	Target	Incidence of Infusion Reactions
Trastuzumab	HER-2	40%
Alemtuzumab	CD52	10-35% had Grade ³ 3
Natalizumab	a4-integrin	11-24%
Tocilizumab	IL-6	8%, Fatal Anaphylaxis
Bevacizumab	VEGF	3%
True Human™		
Xilonix™	IL-1a	0.0005%

Completed Phase III Double-Blinded Placebo Controlled Study for Xilonix™ in Colorectal Cancer

The Phase III study succeeded with respect to the prospective primary *and* secondary endpoints for Xilonix therapy in patients with advanced colorectal cancer. A Marketing Authorization Application (MAA) has been submitted to the European Medicines Agency to seek approval for sale in Europe.

Patients enrolled in the Phase III study had metastatic or unresectable colorectal cancer after failure or intolerabilty of oxaloplatin or irinotecan regimens. Many patients had also failed additional other therapies. Xilonix therapy showed excellent safety and tolerability in this advanced, even infirm population, where patients had multiple symptoms, functional impairment, and included individuals over 70 years of age.

Colorectal cancer is the 2nd leading cause of cancer in the industrialized world and at least half of patients diagnosed will succumb to the disease. Incidence of colorectal cancer parallels economic development, and with economic growth the incidence is rising worldwide. Since currently half of all patients diagnosed with the disease will progress to advanced, metastatic disease and ultimately succumb to the disease, there is a substantial and growing unmet medical need for a therapy for patients with advanced colorectal cancer. Xilonix is the first anti-tumor therapy developed to address specific disease-related morbidities of advanced colorectal cancer.

Xilonix has continually showed an absence of frank toxicity, and in the Phase III colorectal cancer study the antibody acted to reduce progression of morbidity associated with advanced colorectal cancer. Notably, the therapy mediated its anti-cancer activity without apparent compromise to host immunity, thereby eliminating what has been one of the most important and troubling risk factors for anti-cancer therapy in advanced disease.

The Phase III study was specifically designed to evaluate therapy in a group of patients with advanced colorectal cancer. Patients enrolled were required to have multiple symptoms of disease—each correlating with poor prognosis. Symptoms included: weight loss or elevated systemic inflammation, pain, fatigue or anorexia; and also to have functional impairment, as defined by an ECOG status 1 or 2 and included individuals beyond 70 years of age.

The Phase III primary endpoint to determine efficacy was based demonstrating an improved objective response rate for Xilonix therapy. For the 309 patients that received at least one dose of either Xilonix or placebo, there was a 76% relative improvement in objective response rate for patients receiving test article compared to placebo (p=0.0045). The secondary endpoints in the study were important were established prognosticators of overall survival, namely a measure of paraneoplastic thrombocytosis and systemic inflammation. Xilonix treated patients had an 80% reduction in thrombocytosis (p=0.003), and a 60% reduction in systemic inflammation (p=0.004) compared to placebo, respectively.

In addition to the planned primary and secondary analyses, patients treated with Xilonix were found to be 53% more likely to have stable disease compared to placebo. There was also a 26% reduction in the incidence of Serious Adverse Events (SAEs) in the treatment arm compared to placebo. We are not aware of previous reports for anti-tumour therapy in advanced disease where an effect has been seen with respect to control of disease-related morbidity. Similarly, we are not aware of a previous report of a reduction in SAEs for an anti-tumour therapy compared to a placebo control population (See Table).

We believe the clinical evidence supports the use of Xilonix as a novel therapy for the treatment of advanced colorectal cancer and thus a marketing authorization application has been submitted to the regulatory authorities in Europe. The unique mechanism of action and novel clinical findings suggest a breakthrough anti-tumor therapy to address significant unmet medical needs—namely for treating patients with advanced colorectal cancer that have failed or cannot further tolerate cytotoxic regimens.

Table: Primary, Secondary and Tertiary Analysis

	ITT Population (n=102 vs. 207)					
Primary Efficacy Analysis	Placebo Responders (n)	Xilonix Responders (n)	Placebo Responders (%)	Xilonix Responders (%)	Relative Increase in Response Rate Xilonix	p Value
Responders	19	68	19%	33%	76%	0.0045
Secondary Analysis	Placebo	Xilonix	Placebo (%)	Xilonix (%)	Relative Change	p Value
Median Change in Platelet Counts (1,000/mm^3)	25	5	na	na	80% (reduction)	0.003
Patients with Decreased Serum IL-6	15	64	16%	33%	60% (reduction	0.004
Tertiary Analysis	Placebo	Xilonix	Placebo (%)	Xilonix (%)	Relative Change	p Value
Patients with Stable Disease	12	35	12%	17%	53% (Improvement)	0.12
Number of Serious Adverse Events (SAE)	32	48	31%	23%	26% (Risk reduction)	0.062

[1]RECIST V1.1. p values are for 1-tailed significance testing.

Non-Small-Cell Lung Cancer (NSCLC)

Sixteen evaluable NSCLC patients were treated using MABp1 monotherapy (Xilonix™) as part of the Phase I and II clinical trial for MABp1 (Xilonix™) at MD Anderson Cancer Study in Houston, Texas under IND #105,958. The study design was single arm, and examined radiographic tumor response, change in lean body mass as measured by DEXA, change in quality of life, and overall survival. NSCLC Patients with both pulmonary and non-pulmonary or only non-pulmonary metastases have been reported to have median time to death from date of disease progression of 3.2 months which was reported in *Changes in the Natural History of Non-small Cell Lung Cancer (NSCLC))—Comparison of Outcomes and Characteristics in Patients with Advanced NSCLC Entered in Eastern Cooperative Oncology Group Trials Before and After 1990* (Heather Wakelee and et al, 2006 American Cancer Society).

The NSCLC patients treated with MABp1 monotherapy all entered the study with progressive refractory disease and all had pulmonary and/or non-pulmonary metastasis.

Overall survival for the NSCLC patients treated in this study was 7.6 months, which is notably greater than 3.2 months. Stratification based on prior anti-EGFR therapy revealed a median survival of 9.4 months (IQR 7.6-12.5) for those pretreated with Tarceva® (N=10) versus a survival of 4.8 months (IQR 4.3-5.7) for those without (N=6, logrank p=0.187).

The first figure below compares patient overall survival after treatment with MABp1 with that observed in another study with Tarceva®, a drug recently approved for treating NSCLC. The median survival for patients treated with Xilonix™ was 7.6 months. It should be noted that 63% of the Xilonix™ patients had taken Tarceva® and failed. This compares with median survival for a similar patient population treated with Tarceva®, which is a historical control group, where survival was only 6.7 months. Overall survival in the control population in the Tarceva® study was 4.7 months. The comparison between overall survival observed with Xilonix™ and that of the Tarceva® study should be viewed with caution, since the patient populations or supportive care or other factors may have been different between the two studies making direct comparison difficult.

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The second figure compares overall survival of MABp1 treated patients based on whether or not they received pre-treatment with Tarceva®. These findings suggest a remarkable interaction between Tarceva® pre-treatment and MABp1. Survival in the Tarceva® pre-treated group was nearly double compared to those who had not received Tarceva® previously.

When overall survival was analyzed according to pre-treatment status, it was found that having received, but failed Tarceva®, correlated with significantly increased survival. The Kaplan-Meier curves compare survival of patients who had either received and failed (green line) or had not received (gray line) treatment of Tarceva® prior to receiving MABp1 treatment. This subset analysis reveals that patients who had received Tarceva® treatment prior to receiving MABp1 live longer on average than patients who did not receive Tarceva®. This type of analysis may help in designing future trials of MABp1.

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Colorectal Cancer

Results from a Phase II Randomized Study in Cardiovascular Disease

XBiotech completed a multi-center Phase II clinical study in cardiovascular medicine with 43 patients in 2013 (IND #110,908). The study was conducted at nine investigative sites in the United States. This Phase II randomized, controlled clinical study evaluated the therapeutic antibody MABp1 for its ability to reduce adverse events after balloon angioplasty, atherectomy or stent placement in patients undergoing revascularization procedures for blockage of a major artery (superficial femoral artery or SFA) in the leg. Interim data from this study was submitted to the FDA and resulted in fast track designation for this drug development program in the fall of 2012.

While the study was exploratory in nature and not powered with patient numbers to provide a statistically significant outcome, clinical results to date have shown an important trend towards the reduction of restenosis, and reduced incidence of Major Adverse Cardiovascular Events (MACE) in treated patients compared to controls. Patients were monitored for restenosis, or MACE, including heart attack or stroke.

All of the subjects included in this trial had symptomatic peripheral vascular disease, characterized by claudication, rest pain, or limited gangrene. All patients had hemodynamically significant occlusion of the femoral artery. Subjects eligible for enrollment had to be undergoing endovascular intervention as a part of standard of care treatment. Enrolled subjects were randomized to receive (i) study drug plus standard of care or (ii) standard of care following surgery.

Data analyzed from the study suggests a beneficial treatment effect at 15 weeks. The patients received intravenous infusions of MABp1 at day 0 peri-operative, and at days 14, 28 and 42 post-operative. At 15 weeks no patients (0/22) in the treatment arm had experienced re-occlusion (restenosis) of the treated artery, whereas 3 patients (3/21) had restenosis in the control arm. Three patients (3/22) had MACE in the treatment arm, compared to 5 (5/21) in the control group.

These data, together with the FDA fast track designation, have supported advancement of the clinical trial program for the treatment of vascular injury and disease.

Dermatology

Inflammatory skin conditions encompass a wide range of diagnoses from common conditions such as acne, eczema, and psoriasis, to more rare conditions such as pyoderma gangrenosum. One common factor unifying the pathophysiology of these conditions is IL-1a, a pro-inflammatory cytokine present in keratinocytes and inflammatory cells present in skin lesions. We believe that blockade of IL-1a will prove to be a safe and effective treatment for numerous dermatologic conditions.

Psoriasis

XBiotech completed a multicenter, single arm Phase II study of MABp1 in eight patients with moderate to severe plaque psoriasis (IND #112,459). This clinical trial was launched after a dramatic response was observed in a psoriasis patient who was treated with MABp1 on a compassionate basis. The patient seen was a 48 year-old male with Type I psoriasis vulgaris. After a single treatment, the patient showed almost complete resolution of psoriasis lesions within 10 days. The Phase II exploratory study involved providing psoriasis patients three subcutaneous injections of the antibody to evaluate safety, pharmacokinetics and preliminary efficacy of the treatment. Numerous efficacy assessments were made, including the Psoriasis Area and Severity Index (PASI) and performance measures, assessed with the use of the Dermatology Life Quality Index (DLQI) Questionnaire and Physicians Global Assessment (PGA). Findings revealed rapid improvement in patients treated with MABp1, with a median response of 43% improvement in PASI score in just 35 days[1].

Acne

A Phase II exploratory study launched in 2012 and completed in 2013 evaluated MABp1 therapy in moderate to severe acne vulgaris (IND #112,459). The acne study was a single-arm, multicenter study conducted in the United States. This study examined changes in the number of inflammatory acne lesions, as well as patient reported changes in psychiatric symptoms. Eleven patients were administered open-label, subcutaneous injections of MABpl over a six-week period (ClinicalTrials.gov NCT01474798). Objectives were assessment of safety, change in inflammatory lesion count and change in psychosocial functioning using two validated questionnaires.

Patients showed significant improvement in the number of facial inflammatory lesions after treatment with MABp1. Median inflammatory lesion counts decreased 36% (IQR -44% to 1%). Anxiety scores improved (from median 6 to 1) as well as self-image assessment (2.3±0.9 to 2.1±0.1) as measured by the Hospital Anxiety and Depression Scale and the modified Body Image Disturbance Questionnaire, respectively. There were no serious adverse events, or adverse events greater than grade I.

Diabetes (Type II)

XBiotech conducted a Phase II pilot study to test MABp1 in seven patients with Type II diabetes at the University Hospital in Basel, Switzerland. The study was headed by an endocrinologist and expert on the role of inflammatory disease in diabetes, Dr. Marc Donath, Head of Endocrinology, Diabetes and Metabolism at University Hospital of Basel. This study was conducted with appropriate due diligence and authorization equivalent to a US FDA IND, under the Swiss regulatory authority SwissMedic.

The clinical study assessed safety and pharmacokinetics of MABp1 in the diabetic patient population. The study also examined patients to determine if their diabetes improved, including assessing pancreas function and glucose control.

Patients were given a low dose of MABp1 intravenously every two weeks for a total of four doses (Days 0, 14, 28, and 42). To be eligible for treatment, patients needed to have been diagnosed with Type II diabetes according to American Diabetes Association diagnostic criteria at least three months prior to the study.

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To examine the trend of glycated hemoglobin (HbA1c) levels along the study time points, a trend analysis was performed on patients who completed all visits. Compared to baseline, after the 60 days period of treatment HbAlc was reduced by 0.14±0.21% (p=0.15), fasting C-peptide was increased by 88% (p=0.03), pro-insulin by 48% (p=0.03) and insulin by 74% (P=0.ll). Systolic blood pressure decreased by 11 mmHg (p=0.2). Both HbAlc and blood pressure rebounded to baseline levels thirty days after the end of MABp1 application. Treatment with MABpl was well tolerated and no adverse events occurred during the study. This increase in HbA1c after removal of the drug, further suggested the activity for antibody therapy in these type 2 diabetic patients.

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. To date, XBiotech's patent portfolio consists of 16 patent families, and includes 39 issued/allowed patents and approximately 100 pending patent applications in various countries around the world. XBiotech's IP portfolio is designed to protect XBiotech's drug products, therapies and to some extent, its discovery technology. It includes patents and applications that protect MABp1 as a composition of matter and methods of using anti-IL-1a antibodies for the treatment of various diseases including cancer, vascular disorders, inflammatory skin diseases, diabetes, and arthritis. XBiotech's IP portfolio also includes patents and applications directed to some aspects of our proprietary antibody discovery platform, as well as treating *S. aureus* infections.

With respect to its 39 issued/allowed patents, XBiotech owns the rights to the patent families as described in more detail below.

A. Interleukin-1 Alpha Antibodies and Methods of Use. This patent family relates to the development of specific True Human™ monoclonal antibodies, including MABp1, that include (i) an antigen-binding variable region that exhibits very high binding affinity for human IL-1a and (ii) a constant region that is effective at both activating the complement system though C1q binding and binding to several different Fc receptors. XBiotech has been granted 25 patents in this family for interleukin-1 alpha antibodies and methods of use; including ten in the U.S. (two allowed, but not issued), four in Australia, one in China, one in Hong Kong, two in Israel, one in Japan, one in Mexico, one in New Zealand, one in the Philippines, one in Russia and two in South Africa. Patents in this family have a term at least through 2029.

B. Treatment of Cancer with Anti- IL-1 Antibodies. This patent family relates to the use of anti- IL-1 antibodies to inhibit the metastatic potential of tumors by interrupting the physiological role tumor-derived IL-1 plays in tumor metastasis. XBiotech has been granted three patents for this family; including one in Australia, one in Canada and one in Europe. Patents in this family have a term at least through 2027.

C. Treatment of Neoplastic Diseases. This patent family relates to the administration of anti- IL-1 antibodies to treat various tumor-associated diseases and the administration of a monoclonal antibody that specifically binds IL-1 to reduce the size of tumors in human patients suffering from cancer. We have been issued one patent in New Zealand. Patents in this family have a term at least through 2027.

D. Diagnosis, Treatment, and Prevention of Vascular Disorders. This patent family relates to methods of diagnosing, treating and preventing a variety of vascular disorder using IL-1 autoantibody. We have been issued six patents in this family, including one in the U.S., two in Australia, two in Europe and one in Japan. Patents in this family have a term at least through 2027.

E. Compositions and Methods for Treating *S. Aureus* Infections. This patent family relates to new antibodies for treating *S. aureus* infections. XBiotech acquired use of these patents pursuant to its exclusive license agreement with STROX Biopharmaceuticals, LLC. This patent family includes three patents in the U.S. and one patent in Australia.

Patents in this family have a term at least through 2027.

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Because the patent positions of pharmaceutical, biotechnology, and diagnostics companies are highly uncertain and involve complex legal and factual questions, the patents owned and licensed by us, or any future patents, may not prevent other companies from developing similar or therapeutically equivalent products or ensure that others will not be issued patents that may prevent the sale of our products or require licensing and the payment of significant fees or royalties. Furthermore, to the extent that any of our future products or methods are not patentable, that such products or methods infringe upon the patents of third parties, or that our patents or future patents fail to give us an exclusive position in the subject matter claimed by those patents, we will be adversely affected. We may be unable to avoid infringement of third party patents and may have to obtain a license, defend an infringement action, or challenge the validity of the patents in court. A license may be unavailable on terms and conditions acceptable to us, if at all. Patent litigation is costly and time consuming, and we may be unable to prevail in any such patent litigation or devote sufficient resources to even pursue such litigation.

Employees

At December 31, 2015, we had 78 employees, 13 of whom hold a Ph.D. or M.D. (or equivalent) degree. None of our employees are represented by a labor union or covered by a collective bargaining agreement, nor have we experienced work stoppages. We believe that relations with our employees are good.

Corporate Information

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 Schweiz AG, a wholly-owned subsidiary of the Company, was incorporated in Zug, Switzerland in August 2010. XBiotech Japan KK, a wholly-owned subsidiary of the Company, was incorporated in Tokyo, Japan in March 2013. XBiotech GmbH, a wholly-owned subsidiary of the Company, was incorporated in Germany in January 2014.

The Company’s headquarters are located in Austin, Texas.

Investor Information

We maintain an Internet website at http://www.xbiotech.com. The information on our website is not incorporated by reference into this annual report on Form 10-K and should not be considered to be a part of this annual report on Form 10-K. Our reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, our quarterly reports on Form 10-Q and our current reports on Form 8-K, and amendments to those reports, are accessible through our website, free of charge, as soon as reasonably practicable after these reports are filed electronically with, or otherwise furnished to, the SEC. We also make available on our website the charters of our audit committee, compensation committee, nominating and corporate governance committee, as well as our corporate governance guidelines and our code of business conduct and ethics. In addition, we intend to disclose on our web site any amendments to, or waivers from, our code of business conduct and ethics that are required to be disclosed pursuant to the SEC rules.

ITEM 1A RISK FACTORS

Risks Related to our Financial Condition and Capital Requirements

We have incurred significant losses every quarter since our inception and anticipate that we will continue to incur significant losses in the future.

We are a clinical-stage pharmaceutical company with no revenue and a limited operating history. 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, or otherwise, to date, and we continue to incur significant research, development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred losses in every reporting period since our inception in 2005. For the years ended December 31, 2013, 2014, and 2015, we reported a net loss of $9.9 million, $21.7 million, and $37.1 million respectively. As of December 31, 2015, we had an accumulated deficit since inception of $130.3 million.

We expect to continue to incur significant expenses and operating losses for the foreseeable future. We anticipate these losses will increase as we continue the research and development of, and seek regulatory approvals for Xilonix™ and any of our other product candidates, 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 and expected future losses have had, and will continue to have, an adverse effect on our financial condition. If Xilonix™ or any other product candidate fails in clinical trials or does not gain regulatory approval, or if approved and fails to achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. We will need to raise significant additional funding, which may not be available on acceptable terms, if at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our product development efforts or other operations.

Since inception, we have dedicated a majority of our resources to the discovery and development of our proprietary preclinical and clinical product candidates, and we expect to continue to expend substantial resources doing so for the foreseeable future. These expenditures will include costs associated with conducting research and development, manufacturing product candidates and products approved for sale, 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 ending December 31, 2015, we recognized approximately $31.3 million in expenses associated with research and development and clinical trials.

We completed our initial public offering on April 15, 2015. However, the net proceeds from the offering 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. Accordingly, we may require substantial additional capital beyond the offering to continue our clinical development and potential commercialization activities. Our future capital requirements depend on many factors, including but not limited to:

- the number and characteristics of the 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 Xilonix™ 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 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. We may need to seek additional funds sooner than planned, through public or private equity or debt financings, government or other third-party funding, marketing and distribution arrangements

and other collaborations, strategic alliances and licensing arrangements or a combination of these approaches. 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.

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.

We are subject to two related shareholder class action lawsuits, which may adversely affect our business, financial condition, results of operations and cash flows.

We and certain of our executive officers and directors are defendants in a federal securities class action lawsuit and in a similar securities class action filed in state court in California. These lawsuits, including their current status, are described in Part I, Item 3 “Legal Proceedings” in this Form 10-K. While we believe these lawsuits to be without merit and intend to vigorously defend them, we are in the early stages of both cases and we cannot guarantee any particular outcome. These and any similar future matters may divert our attention from our ordinary business operations, and we may incur significant expenses associated with them (including, without limitation, substantial attorneys’ fees and other fees of professional advisors and potential obligations to indemnify the underwriter for our initial public offering and current and former officers and directors who are or may become parties to or involved in such matters). Depending on the outcome of such matters, we could be required to pay material damages and/or suffer other penalties, remedies or sanctions. Accordingly, the ultimate resolution of these pending matters or any similar future matters could have a material adverse effect on our business, financial condition, results of operations, cash flows, liquidity and ability to meet our debt obligations and could negatively impact the trading price of our common stock. Any existing or future shareholder lawsuits could also adversely impact our reputation, our relationships with our customers and our ability to generate revenue.

Risks Related to Our Business

We currently have no source of product revenue and may never become profitable.

To date, we have not generated any revenues from commercial product sales, or otherwise. 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 Xilonix™ or any future product candidates that we may develop, in-license or acquire in the future. Even if we are able to achieve regulatory approval successfully for Xilonix™ or any 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 Xilonix™ or any of our other 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 Xilonix™ 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 payors, including government and private payors;
- 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 Xilonix™ or any other 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 when or if we will be able to achieve or maintain 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 Xilonix™ or any other product candidates, we anticipate incurring significant costs associated with commercializing these products.

Even if we are able to generate revenues from the sale of Xilonix™ or any other product candidates that may be approved, we may not become profitable and may need to obtain additional funding to continue operations. If we fail to become profitable or 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 Xilonix™ and any of our other product candidates.

We do not have any products that have gained regulatory approval. Our lead product, Xilonix™, is currently in a Phase III clinical trial in the United States and completed a Phase III clinical trial during Q4 2015 in Europe, respectively. As a result, our near-term prospects, including 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 Xilonix™ in a timely manner. We cannot commercialize Xilonix™ or our other product candidates in the United States without first obtaining regulatory approval for each product from the FDA; similarly, we cannot commercialize Xilonix™ or our other product candidates outside of the United States 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 Xilonix™ or any of our other potential product candidates for a target indication, we must demonstrate with substantial evidence gathered in preclinical and well-controlled clinical studies, generally including two well-controlled Phase III trials, and, with respect to approval in the United States, to the satisfaction of the FDA, 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 Xilonix™ or our 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 Xilonix™ or any of our other product candidates were to successfully obtain approval from the FDA and 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 study or risk management requirements. If we are unable to obtain regulatory approval for Xilonix™ 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 any of Xilonix™ or our other product candidates, once obtained, may be withdrawn. Furthermore, even if we obtain regulatory approval for Xilonix™, the commercial success of Xilonix™ will depend on a number of factors, including the following:

- development of a commercial organization 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 payors;
- our ability to manufacture quantities of Xilonix™ using commercially sufficient 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 Xilonix™;
- 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 of Xilonix™ as safe and effective by patients and the medical community; and
- a continued acceptable safety profile of Xilonix™ following approval.

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

We recently submitted a Marketing Authorization Application the EMA for Xilonix™ after successfully completing a Phase III clinical trial in Europe. Even if the EMA approves Xilonix™ there are a number of obstacles to consider in the post-marketing approval and commercialization processes in Europe.

On March 7, 2016, we submitted our Marketing Authorization Application, or MAA, to the EMA Center for Human Medicinal Products, or CHMP, for the Phase III clinical trial of Xilonix™ completed in Europe during Q4 2015. The regulatory assessment process at the EMA is both long and expensive and may not lead to a subsequent approval. In the initial MAA submission to the EMA, the regulatory body must validate the application prior to its official assessment. As of March 14, 2016 we are currently undergoing the content validation stage of the submission. The EMA can return with questions about the content and require specific updates or changes. This can delay our timeline or result in halting of our application process before reaching the assessment phase.

We have been approved for review under the Centralised Procedure at the EMA, which generally means that it takes 210 days. However, we submitted a request to the EMA to be reviewed under the Accelerated Assessment procedure, which has a general duration of 150 days. We may not be approved for the Accelerated Assessment procedure, which can delay the timeline of learning of the EMA decision on the overall assessment of our application. Furthermore, the EMA has the ability to "stop the clock" of the assessment timeline if there are any questions about the application that arise. We are given a specific amount of time to respond to such questions, and must do so to the satisfaction of the EMA before the clock resumes. This can cause further delays and overall uncertainty as to when we receive an official decision as to whether or not our application is approved.

During the assessment period, our manufacturing facilities will most likely be audited. They must meet the standards of Good Manufacturing Practices, or GMP. If the GMP inspectors assigned to auditing the manufacturing facilities finds any violations we may experience potential challenges in the overall approval and assessment process, and potentially, the ability to commercially manufacture Xilonix™. Additionally, our new manufacturing facility is scheduled to go through validation with the EMA. The new facility might fail validation or not meet EMA standards for a commercial manufacturing facility. Also, during the assessment period, our clinical research sites engaged to recruit patients into the clinical trial, will most likely be audited to ensure standards of Good Clinical Practice, or GCP. The EMA could have findings showing that our clinical research sites, or other aspects of the trial failed to meet GCP standards potentially impacting or delaying approval.

There are a few possibilities surrounding the regulatory approval status of Xilonix™ at the EMA: 1) The EMA may not approve Xilonix™ due to our failure to prove our endpoints to the satisfaction of the CHMP committee members, who may be different individuals or share a different thinking from the Scientific Advice Working Group at the EMA whom we worked with to design the trial, thus there may be a general lack of buy-in from the reviewing committee, or other unforeseeable disagreement with the study design; 2) The EMA may approve Xilonix™ , but with caveats such as conducting follow up clinical trials to show further safety data or additional data for endpoints established in the study protocol. Conducting additional studies would be expensive and time consuming, and present further roadblocks to full approval and commercialization, thus preventing us from generating revenue for the company; or 3) The EMA may approve Xilonix™. If the EMA approves Xilonix™ there are additional steps we must take for full marketing and commercialization of the product. EMA approval does not guarantee country specific reimbursement across the EU. We still must pursue review of product for pricing and reimbursement, which requires additional time and cost. Even though the EMA may approve Xilonix™ this does not necessarily guarantee certain EU countries will accept our product for reimbursement. We could face no acceptance for reimbursement in any country, or reimbursement in very few countries, thus minimizing our ability to generate sufficient revenue.

In addition to seeking approval in specific EU countries, we must also gain reimbursement approval, as well as buy-in from patients and health care professionals alike for the use of Xilonix™ to treat advanced metastatic colorectal cancer. If we do not receive reimbursement from country or private payers in the EU, Xilonix™ may not reach or be accessible to patients or health care professionals. Even if Xilonix™ is approved for reimbursement in EU countries, it may not always maintain its reimbursement status. Some countries may decide to no longer reimburse Xilonix™ for unforeseeable reasons. Further, patients and health care professionals may reject Xilonix™ as a reasonable standard of care treatment for advanced metastatic colorectal cancer. If patients and healthcare professionals reject Xilonix™ as a treatment for advanced metastatic colorectal cancer, then it will be difficult to generate revenue for the company.

If Xilonix™ is approved by the EMA, we do not have the appropriate personnel engaged as employees to conduct an effective marketing and commercialization strategy. As a result, we must pursue a strategic partnership through a contractual arrangement with an organization with the appropriate expertise. The cost-benefit of such an arrangement may not actualize profit and generate revenues on a short-term basis. Because we would entrust commercialization to an outside organization, there may be any number of issues that arise that we cannot foresee.

Because the results of earlier clinical trials are not necessarily predictive of future results, Xilonix™, which is currently in an on-going Phase III clinical trial as well as a recently completed Phase III clinical trial, or any other product candidate 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. Despite the results reported in earlier clinical trials for Xilonix™, 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 Xilonix™ or any of our other 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 applicable foreign regulatory authorities may not agree and may require us to conduct additional clinical trials. If later-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 Research Organizations ("CRO's") and 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 performance. We may experience delays in enrolling subjects in our trials and may not be able to enroll sufficient subjects to complete the trials.

If we experience delays in the completion or termination of, any clinical trial of Xilonix™ or any 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 Xilonix™ or our other 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 Xilonix™ or our other 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 many years following the commencement of preclinical studies and clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. 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 neither Xilonix™ nor any other 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:

- disagreement over the design or implementation of our clinical trials;

- failure to demonstrate that a product candidate is safe;
- 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 Xilonix™ or our other 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 process; 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, Xilonix™ or our other 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 Xilonix™ or our other product candidate produces 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 on us. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

Even if we believe our 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 Xilonix™ or our other product candidates to permit 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 effect 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.

Xilonix™ or our other 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 Xilonix™ or our other 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 discontinuance of further development of Xilonix™ or other 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. To date the majority of adverse events observed in clinical trials of Xilonix™ have been mild and have not resulted in discontinuation of therapy. There have been no serious side effects observed that appear to be related to administration of Xilonix™ in our clinical trials. There can be no assurance that side effects from Xilonix™ in future clinical trials will continue to be mild or that side effects in general will not prompt the discontinued development of Xilonix™ or other 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 Xilonix™ or any other product candidates, which could prevent us from ever generating revenues or achieving 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 Xilonix™ or any of our other 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 Xilonix™ or our other product candidates receive regulatory approval, they may still face future development and regulatory difficulties.

Even if we obtain regulatory approval for Xilonix™ or another product candidate, 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 Xilonix™ or any other 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 Xilonix™, 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 Xilonix™ or any other 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 United States will be heavily scrutinized by the FDA, the Department of Justice, or the DOJ, the Office of Inspector General of the Department of Health and Human Services, or 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 United States will be heavily scrutinized by comparable foreign regulatory authorities.

In the United States, 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 agreements that materially restrict the manner in which we promote or distribute our drug products. These false claims statutes include the federal False Claims Act, which 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, these 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 claim action, pay settlement fines or restitution, agree to comply with burdensome reporting and compliance obligations, and be excluded from the 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 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 Xilonix™ or any other 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 achieve or sustain profitability.

Failure to obtain regulatory approval in foreign jurisdictions would prevent Xilonix™ or any other 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 United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, 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 United States 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 United States 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 Xilonix™ for any of our other 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 Xilonix™ or our other product candidates, the products may not receive coverage and adequate reimbursement from third-party payors, 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 payors. Patients who are prescribed medications for the treatment of their conditions generally rely on third-party payors 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 Xilonix™ or our other 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 payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Third-party payors may also seek additional clinical evidence, beyond the data required to obtain marketing approval, demonstrating clinical benefits and value in specific patient populations before covering our products for those patients. We cannot be sure that coverage and adequate reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement are not available or are available only at limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

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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 not be sufficient 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 payors 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 United States. Coverage and reimbursement for drug products can differ significantly from payor to payor. 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 payors 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 payors 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 an infrastructure for the sales, marketing and distribution of pharmaceutical drug products and 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 become profitable. We will be competing with many companies that currently 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, we may be unable to compete successfully against these more established companies.

Xilonix™ and our other product candidates, if approved, may not achieve adequate market acceptance among physicians, patients, and healthcare payors and others in the medical community necessary for commercial success.

Even if we obtain regulatory approval for Xilonix™ or any of our other product candidates, such product(s) may not gain market acceptance among physicians, healthcare payors, patients or the medical community. Our commercial success also depends on coverage and adequate reimbursement of our product candidates by third-party payors, including government payors, 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 payors 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.

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

Our Research Programs May Not Succeed.

At this time we have a number of programs in pre-clinical as well as early to late stages of clinical development including:

- Metastatic Colorectal Cancer (mCRC)
- Non-Small Cell Lung Cancer (NSCLC)
- Atherosclerosis
- Pyoderma Gangrenosum
- Staphyloccocus Aureus
- Clostridium Difficile
- Ebola

In the past several months, XBiotech has positioned itself with a pipeline of potential drug candidates at a variety of stages, from development and pre-clinical through Phase III. 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:

- 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
- If a clinical trial is completed, we may not have the appropriate personnel to submit a marketing application to regulatory authorities for approval
- Regulatory authorities may reject drug candidates for a variety of reasons, preventing us to proceed with marketing and commercialization of approved products
- We may run out of 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 based on our current drug candidate 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. XBiotech's promises regarding donation of five percent of any gross revenues from an Ebola drug developed using the blood sample it received may adversely impact XBiotech and its shareholders. 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 payors will decide to add 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 lead product candidate, Xilonix™ for the treatment of colorectal cancer from Vectibix® by Amgen; Erbitux by Bristol Myers Squibb; Cyramza ® by Eli Lilly and Company and Avastin by Genentech/Roche. Our competitors in the other therapeutic categories that we are addressing which are non-small cell lung cancer, restenosis in peripheral vascular disease, diabetes and psoriasis are Humira from AbbVie, Remicade and Stellara from J&J, Enbrel from Amgen and Necitmumab from Eli Lilly and Company. In the infectious disease area, there are no currently approved monoclonal antibody products, although many have been tried. The leading small-molecule antibiotics are Vancomycin, originally from Eli Lilly and Company now in a generic form from Baxter, Sandoz, Akorn and Hospira; Cubicin (Daptomycin) from Cubist and Dalvance from Durata.

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 also 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 Xilonix™ or any of our other product candidates. In addition, many companies are developing new therapeutics, and 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 other than Xilonix™ 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 most advanced product candidate, Xilonix™, a key element of our growth strategy is to acquire, develop and/or market additional products and product candidates. All of these potential product candidates remain in the discovery and clinical study stages. Research programs to identify product candidates require substantial technical, financial and

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

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

We face an inherent risk of product liability exposure related to the testing of Xilonix™ and any other 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 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 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 intend to obtain insurance coverage for products to include the sale of commercial products if we obtain marketing approval for Xilonix™ or our other 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, and we may experience difficulties in managing this growth.

As of March 13, 2016, we had 84 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 being conducted at numerous clinical sites;
- 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 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, and many members of our current management team are new. 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 Medical Director, our Senior Vice President of Operations, our Vice President of Manufacturing, our Vice President of Quality, our Director of Research and Development, our Director of Quality Control and our Vice President of Finance and Human Resources. 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. Competition for qualified personnel is particularly intense in the Austin area, where our headquarters

are located. Our failure to 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 United States 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 workers' compensation insurance 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 also may result in substantial fines, penalties or other sanctions.

Business disruptions could seriously harm our future revenues and financial condition and increase our costs and expenses.

Our operations could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics 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 or other business interruption. The ultimate impact on us, our significant suppliers and our general infrastructure of being consolidated in certain geographical areas is unknown, but our operations and financial condition could suffer in the event of a major earthquake, fire or other natural disaster. Further, any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our business, results of operations, financial condition and cash flows from future prospects.

Risks Related to Intellectual Property

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

We depend on our ability to protect our proprietary technology. We rely on trade secret, patent, copyright and trademark laws, and confidentiality, licensing and other agreements with employees and third parties, all of which offer only limited protection. Our commercial success will depend in large part on our ability to obtain and maintain patent protection in the United States 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 United States 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 United States. 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 any of existing patents or pending patent applications for any of our technologies or product candidates will result in the issuance of patents that protect such technologies or products 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 United States 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, may 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 MABp1 or our 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 United States 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 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 adversely affected.

If our products, methods, processes and other technologies infringe 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 United States 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 litigation and prevent you from being able to sell your shares at or above the offering price.

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;
- 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. 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 after this offering does not exceed the initial public offering price, you may not realize any return on your investment in us and may lose some or all of your investment.

Insiders have substantial control over our company after our initial public offering in April 2015 and could delay or prevent a change in corporate control.

Right after our April 2015 offering, our directors, executive officers and principal shareholders, together with their affiliates, beneficially own, in the aggregate, at least 10 million shares or approximately 32% of our outstanding common stock, and could own up to 13 Million shares or 40% of our outstanding common stock if they fully exercise their outstanding stock options or shares. 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 our 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 our company;
- impeding a merger, consolidation, takeover or other business combination involving our company; or
-

discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of our company.

We have broad discretion in the use of the net proceeds from our initial public offering in April 2015 and may not use them effectively.

We intend to continue to allocate the net proceeds that we received from the April 2015 offering as described below in the "Use of Proceeds" section of our Prospectus. However, our management will have broad discretion in the actual application of the net proceeds, and we may elect to allocate proceeds differently from that described in "Use of Proceeds" if we believe it would be in our best interests to do so. Our shareholders may not agree with the manner in which our management chooses to allocate and spend the net proceeds. The failure by our management to apply these funds effectively could have a material adverse effect on our business. Pending their use, we may invest the net proceeds from this offering in a manner that does not produce income or that loses value.

Provisions in our charter documents and under Canadian law could make an acquisition of us, which may be beneficial to our shareholders, more difficult and may prevent attempts by our shareholders to replace or remove our current management.

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 shares.

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 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.

For US federal income taxation purposes, we will be a passive foreign investment company, or 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 subsequent years in which they are held by that person. Because in the past our gross income consisted mostly of interest, we have been a PFIC in prior taxable years. We may also be a PFIC in future taxable years. Gain realized by a US investor from the sale of PFIC shares is taxed as ordinary income, as opposed to capital gain, and subject to an interest charge unless the US person has timely made one of the tax elections described in the section titled "Material United States and Canadian Tax Considerations—US Material Federal Income Tax Consequences."

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, or the DGCL, which may be of most interest to shareholders include the following: (i) for material corporate transactions (such as

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 for similar material corporate transactions; (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 shares 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 shares less attractive because of these material differences. If some investors find our common shares less attractive as a result, there may be a less active trading market for our common shares and our share price may be more volatile.

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

Future sales of a substantial number of our common shares, or the perception that such sales will occur, could cause a decline in the market price of our common shares. As at December 31, 2015, we had 32,279,106 common shares outstanding. This includes the common shares sold in the April 2015 offering,

In the future, we may issue additional common shares or other equity or debt securities convertible into common shares 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.

We are an "emerging growth company" as that term is used in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and we intend to take advantage of reduced disclosure and governance requirements applicable to emerging growth companies, which could result in our common stock being less attractive to investors and adversely affect the market price of our common stock or make it more difficult to raise capital as and when we need it.

We are an "emerging growth company" as that term is used in the JOBS Act, and we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved and exemptions from any rules that the Public Company Accounting Oversight Board may adopt requiring mandatory audit firm rotation or a supplement to the auditor's report on the financial statements. We currently intend to take advantage of some, but not all, of the reduced regulatory and reporting requirements that will be available to us under the JOBS Act, so long as we qualify as an "emerging growth company." For example, so long as we qualify as an "emerging growth company," we may elect not to provide you with certain information, including certain financial information and certain information regarding compensation of our executive officers, that we would otherwise have been required to provide in filings we make with the Securities and Exchange Commission, or SEC, which may make it more difficult for investors and securities analysts to evaluate our company.

We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. 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 stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company, which in certain circumstances could be for up to five years. See section in our Prospectus titled, "Prospectus Summary—Implications of Being an Emerging Growth Company."

Because of the exemptions from various reporting requirements provided to us as an "emerging growth company" we may be less attractive to investors and it may be difficult for us to raise additional capital as and when we need it. Investors may be unable to compare our business with other companies in our industry if they believe that our financial accounting is not as transparent as other companies in our industry. If we are unable to raise additional capital as and when we need it, our business, results of operations, financial condition and cash flows and future prospects may be materially and adversely affected.

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 shares.

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 shares.

We will be required to disclose changes made in our internal controls and procedures on a quarterly basis and our management will be required to assess the effectiveness of these controls annually. However, for as long as we are an "emerging growth company" under the JOBS Act, 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. We could be an "emerging growth company" for up to five years. An independent assessment of the effectiveness of our internal controls could detect problems that our management's assessment might not.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

Our operations are based primarily in Austin, Texas. On January 12, 2008, the Company entered a lease agreement to lease its facility in Austin, Texas, USA. On September 15, 2010, the Company entered into a second lease agreement to lease additional space in Austin, TX, USA. On March 20, 2013, the Company extended the lease for another 21 months with the same terms and rental rates as the current lease. We have grown our workforce significantly over the past year and expect to continue to add a significant number of additional employees during 2016. To accommodate larger-scale commercial manufacturing needs, we purchased 48 acres of industrial-zoned property located five miles from Austin's central business district. In September 2014, we commenced ground-breaking on a new manufacturing facility on this property. All construction activities are on schedule per the current project plan with anticipated building completion in March of 2016 and validation of product in July 2016.

ITEM 3. LEGAL PROCEEDINGS

On December 1, 2015, a purported securities class action complaint captioned *Yogina Rezko v. XBiotech Inc., John Simard, Queena Han and WR Hambrecht & Co., LLC* was filed against us, certain of our officers and directors and the underwriter for our initial public offering in the Superior Court for the State of California, Los Angeles County.

On December 2, 2015, a purported securities class action complaint captioned *Linh Tran v. XBiotech Inc., John Simard and Queena Han* was filed against us and certain of our officers and directors in U.S. District Court for the Western District of Texas. The lawsuits are based on substantially similar factual allegations and purport to be class actions brought on behalf of purchasers of the Company's securities during the period from April 15, 2015 through November 23, 2015. The complaint filed in California state court alleges that the defendants violated the Securities Act of 1933, as amended (the "Securities Act"), and the complaint filed in federal court alleges that the defendants violated the Securities Exchange Act of 1934, as amended (the "Exchange Act"), in each case by making materially false and misleading statements concerning the Company's Phase III clinical trial conducted in Europe to assess Xilonix™ as a treatment for colorectal cancer. The California complaint purports to assert claims for violations of Sections 11, 12(a)(2) and 15 of the Securities Act, and the federal complaint purports to assert claims for violation of Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder. Both complaints seek, on behalf of the purported class, an unspecified amount of monetary damages, interest, fees and expenses of attorneys and experts, and other relief.

Both the federal case and the California case are in the early procedural stages. On February 24th, 2016, following a proceeding to select a lead plaintiff in the federal case, the court issued an order appointing Mr. Kresimir Corak as lead plaintiff. We expect that the plaintiff will file an amended complaint in the federal case in April 2016. In the California case, we expect to make certain procedural motions in May 2016. No trial or other dates have been set.

ITEM 4. MINE SAFETY DISCLOSURES
Not applicable.

PART II

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

Market Information

Our common stock began trading on The NASDAQ Global Select Market on April 15, 2015 under the symbol "XBIT." Prior to that time, there was no established public trading market for our common stock. The following table sets forth the high and low sale prices per share for our common stock on The NASDAQ Global Select Market for the periods indicated:

Year Ended December 31, 2015:	High	Low
Second Quarter (commencing April 15, 2015)	$31.50	$17.63
Third Quarter	$20.71	$13.87
Fourth Quarter	$15.77	$7.47

Holders of record

At February 22, 2016, there were 1,721 holders of record of our common stock. Because many of our shares are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of beneficial holders represented by these record holders.

Dividends

We have never paid or declared any cash dividends on our common stock. We currently intend to retain any earnings for future growth and, therefore, do not expect to pay cash dividends in the foreseeable future.

Use of Proceeds from IPO

On April 14, 2015, our registration statement on Form S-1 (File No. 333-201813) was declared effective by the Securities and Exchange Commission for our initial public offering pursuant to which we sold an aggregate of 4,000,000 shares of our common stock to investors at a price of $19.00 per share. W.R. Hambrecht + Co., Inc. acted as the sole underwriter. The offering commenced as of April 14, 2015 and did not terminate before all of the securities registered in the registration statement were sold. On April 17, 2015, we closed the sale of such shares, resulting in net

proceeds to us of approximately $70.6 million after deducting underwriting discounts and commissions of $3.8 million and other offering expenses of approximately $1.6 million. No payments were made by us to directors, officers or persons owning ten percent or more of our common stock or to their associates, or to our affiliates.

There has been no material change in the planned use of proceeds from our initial public offering as described in our final prospectus filed with the Securities and Exchange Commission on April 16, 2015 pursuant to Rule 424(b). We are holding the balance of the net proceeds from the IPO in a bank account at CIBC USD account.

ITEM 6. SELECTED FINANCIAL DATA

The following selected consolidated financial data for each of the four years in the period ended December 31, 2015 are derived from our audited consolidated financial statements. The selected consolidated financial data set forth below should be read in conjunction with “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and the financial statements, and the related Notes, included elsewhere in this annual report on Form 10-K. Historical results are not necessarily indicative of future results. Set forth below are our selected consolidated financial data (in thousands, except per share amounts)

	Year Ended December 31,			
	2015	2014	2013	2012
Statement of Operations Data				
Operating expenses:				
Research and development	$31,310	$14,329	$7,935	$13,334
General and administrative	6,200	7,449	1,990	1,829
Total operating expenses	37,510	21,778	9,925	15,163
Loss from operations	(37,510)	(21,778)	(9,925)	(15,163)
Other income (loss):				
Interest income	-	1	1	3
Foreign exchange gain (loss)	6	53	(3)	-
Other income	21	-	-	-
Total other income (loss):	27	54	(2)	3
Net loss	(37,483)	(21,724)	(9,927)	(15,160)
Net loss per common share—basic and diluted	(1.22)	(0.90)	(0.45)	(0.71)
Weighted average number of common shares—basic and diluted	30,801,994	24,162,700	22,220,416	21,294,369

	As of December 31,			
	2015	2014	2013	2012
Balance sheet data				
Cash and cash equivalents	$91,051	$57,329	$7,244	$4,167
Working capital	86,749	54,917	6,848	3,297
Total assets	109,358	62,177	11,073	8,469
Total shareholders’ equity	103,050	59,030	10,228	7,372

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

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and related notes thereto included elsewhere in this annual report on Form 10-. 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 that involve risks and uncertainties. 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.

Overview

XBiotech Inc. is a clinical-stage biopharmaceutical company engaged in discovering and developing True Human™ monoclonal antibodies for treating a variety of different diseases. True Human™ monoclonal antibodies are those which occur naturally in human beings—as opposed to being derived from animal immunization technologies 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. While primarily focused on bringing our lead product candidate, Xilonix™, to market, we have also developed a proprietary True Human™ monoclonal antibody discovery platform and manufacturing system.

We have never been profitable and, as of December 31, 2015, we had an accumulated deficit of $130.7 million. We had a net loss of $37.5 million for the year ended December 31, 2015, compared to $21.7 million for the year ended December 31, 2014, and $9.9 million for the year ended December 31, 2013. We expect to incur significant and increasing operating losses for the foreseeable future as we advance our drug candidates from discovery through preclinical testing and clinical trials and seek regulatory approval and eventual commercialization. In addition to these increasing research and development expenses, we expect general and administrative costs to increase as we add personnel and operate as a public company. We will need to generate significant revenues to achieve profitability, and we may never do so. On April 17, 2015, the Company closed its initial public offering of 4,000,000 shares of its common stock at a price of $19.00 per share for a total offering amount of $76,000,000, before underwriting discounts, commissions and other Company expenses. Net proceeds to the Company totaled approximately $70.6 million after deducting underwriting discounts and commissions of $3.8 million and other offering expenses of approximately $1.6 million. As of December 31, 2015, we had 78 employees.

Recent Events:

Clinical trial and construction of the new manufacturing facility Highlights

As of March 2016, XBiotech has achieved some significant milestones with its Xilonix™ and 514G3 programs. Enrollment on a Phase III Symptomatic Colorectal Cancer Study has been completed and 333 subjects were enrolled. Because the study endpoints were satisfactorily met, XBiotech decided to proceed with the submission of a Marketing Authorization Application to the European Medicines Agency, and possibly other foreign regulatory authorities. Additionally, the final patient for Phase I on a Staphylococcus Aureus Bacteremia Phase I and II Study with a brand new antibody therapy, 514G3, has been enrolled. Phase II will commence once it has been found the final enrolled patient is free of dose-related toxicities.

There was significant progress in 2015 with regard to construction of the new manufacturing facility located in Austin, Texas. During the year the building walls, structural steel, and roofing were installed. Build out of the interior was started in administrative and lab spaces, and the building was prepared for installation of clean rooms. Final engineering designs were completed for the manufacturing spaces with clean room construction commencing in Q4 2015. All activities are on schedule per the current project plan with anticipated building completion in May 2016 and validation of product in July 2016.

Revenues

To date, we have not generated any revenue. Our ability to generate revenue and become profitable depends on our ability to successfully commercialize our lead product candidate, Xilonix™, or any other product candidate we may advance in the future.

Research and Development Expenses

Research and development expense consists of expenses incurred in connection with identifying and developing our drug candidates. These expenses consist primarily of salaries and related expenses, stock-based compensation, the purchase of equipment, laboratory and manufacturing supplies, facility costs, costs for preclinical and clinical research, development of quality control systems, quality assurance programs and manufacturing processes. We charge all research and development expenses to operations as incurred.

Clinical development timelines, likelihood of success and total costs vary widely. We do not currently track our internal research and development costs or our personnel and related costs on an individual drug candidate basis. We use our research and development resources, including employees and our drug discovery technology, across multiple drug development programs. As a result, we cannot state precisely the costs incurred for each of our research and development programs or our clinical and preclinical drug candidates. From inception through December 31, 2015, we have recorded total research and development expenses, including share-based compensation, of $101.1 million. Our total research and development expenses for the year ended December 31, 2015 was $31.3 million, compared to $14.3 million the year ended December 31, 2014, and $7.9 million for the year ended December 31, 2013. Share-based compensation accounted for $2.2 million for the year ended December 31, 2015, compared to $1.3 million for the year ended December 31, 2014 and $0.6 million for the year ended December 31, 2013.

Research and development expenses, as a percentage of total operating expenses for the year ended December 31, 2015 was 83%, compared to 66% for the year ended December 31, 2014, and 80% for the year ended December 31, 2013. The percentages, *excluding* stock-based compensation, for the year ended December 31, 2015 was 88%, compared to 88% for the year ended December 31, 2014 and 80% for the year ended December 31, 2013.

As planned, our clinical costs has increased as we advance Xilonix™ as an anti-cancer therapy for treating last-line metastatic colorectal cancer, under a regulatory pathway through Phase III clinical trials in Europe and the US and when we expand the studies to South America, Israel, Australia and Canada, all territories expected to be active during Q2 2016. Our clinical study underway in Europe, that is regulated by the European Medicines Agency (EMA), completed enrollment in November, 2015. The submission for marketing approval to the EMA was completed in March 2016 which could position the Company to generate related revenues in 2017 if it receives EMA marketing approval and the Company successfully completes its commercialization plan for Xilonix™. The clinical research and development costs will also increase as we have launched a Phase I and II clinical study of novel True Human™ therapeutic antibody for treating serious infections due to *Staphylococcus aureus* in the U.S. We expect to complete expansion of this study into Europe, South Korea and Taiwan for participation in the Phase II portion by the end of Q2 2016. The Company’s plans to pursue an advanced regulatory path for Pyoderma Gangrenosum is on hold indefinitely while we await the outcome of other programs in later stages of development. In the meantime, based on the results of our preclinical studies, we anticipate that we will select drug candidates and research projects for further development on an ongoing basis in response to their preclinical and clinical success and commercial potential. For R&D 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 for the year ended December 31, 2015 was $6.2 million, compared to $7.4 million for the year ended December 31, 2014 and $2.0 million for the year ended December 31, 2013. Share-based compensation accounted for $2.2 million for the year ended December 31, 2015, compared to $5.7 million for the year ended December 31, 2014 and $0.2 million for the year ended December 31,

2013.

Critical Accounting Policies

Our Management's Discussion and Analysis of our 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, or 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.

Stock-Based Compensation

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

Determination of the Fair Value of Stock-Based Compensation Grants

The determination of the fair value of stock-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 and other option valuation models require the input of highly subjective assumptions, including the expected stock price volatility. If we made different assumptions, our stock-based compensation expenses, net loss, and net loss per common share could be significantly different. Prior to our initial public offering in April 2015, we issued common stock for cash consideration to new investors. We believe that such transactions represent the best evidence of fair value of our common stock. Therefore, we used the sales price of our common stock during these periods as the fair value of our common stock.

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

	Year Ended December 31,								
	2015			2014			2013		
Weighted-average grant date fair value per share	$17.95			$8.23			$11.37		
Expected volatility	66%	–	71%	70%	–	73%	73%		
Risk-free interest rate	1.07%	–	2.42%	0.69%	–	2.73%	2.04%	–	3.84%
Expected life (in years)	3	–	10	3	–	10	6.25	–	10
Dividend yield		–			–			–	

We have assumed no dividend yield because we do not expect to pay dividends in the foreseeable future, which is consistent with our past practice. 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.

Results of Operations

Revenue

We did not record any revenue during the years ended December 31, 2015, 2014 and 2013.

Expenses

Research and Development

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

	Year Ended December 31,		Increase	% Increase	Year Ended December 31,		Increase	% Increase
	2015	2014	(Decrease)	(Decrease)	2014	2013	(Decrease)	(Decrease)
Salaries and related expenses	$6,200	$3,826	$2,374	62 %	$3,826	$3,001	$825	27 %
Laboratory and manufacturing supplies	4,325	2,562	1,763	69 %	2,562	928	1,634	176 %
Clinical trials and sponsored research	14,542	3,846	10,696	278 %	3,846	2,095	1,751	84 %
Stock-based compensation	2,204	1,303	901	69 %	1,303	551	752	136 %
Other	4,039	2,792	1,247	45 %	2,792	1,360	1,432	105 %
Total	$31,310	$14,329	$16,981	119 %	$14,329	$7,935	$6,394	81 %

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 by 119% to $31.3 million for year ended December 31, 2015 compared to $14.3 million for the year ended December 31, 2014.

The increase in research and development expenses for the year ended December 31, 2015 compared to the year ended December 31, 2014 was due to a $10.7 million increase of clinical trial activities and sponsored research expense, which results primarily from the clinical trial started in Europe and the US. The increase is also due to higher salaries and related expenses in 2015 due to the growing size of our workforce from 49 to 70, salary increases for current employees and a $330,000 bonus payment to an executive officer in the second quarter of 2015. Laboratory and manufacturing supplies also increased due to the increase of manufacturing processing development activities, research activities and quality control activities. Stock–based compensation increased due the issuance of stock options to new employees.

Research and development expenses increased by $6.4 million to $14.3 million for the year ended December 31, 2014, compared to $7.9 million for the year ended December 31, 2013. This increase was due to a $3.1 million increase in clinical trial activities in Europe and the United States, a $1.6 million increase in research and development use of chemicals, reagents as well as laboratory materials; a $0.8 million increase in salaries and up $0.7 million increase in stock-based compensation.

General and Administrative

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

	Year Ended December 31,		Increase	% Increase	Year Ended December 31,		Increase	% Increase
	2015	2014	(Decrease)	(Decrease)	2014	2013	(Decrease)	(Decrease)
Salaries and related expenses	$1,167	$531	$ 636	120 %	$531	$565	(34)	(6 %)
Patent filing expense	793	471	322	68 %	471	398	73	18 %
Stock-based compensation	2,203	5,717	(3,514)	(61 %)	5,717	188	5,529	2941 %
Professional fees	802	252	550	218 %	252	490	(238)	(49 %)
Other	1,235	478	757	158 %	478	349	129	37 %
Total	$6,200	$7,449	$ (1,249)	(17 %)	$7,449	$1,990	$ 5,459	274 %

General and administrative expenses decreased by 17% to $6.2 million for the year ended December 31, 2015 compared to $7.4 million for the year ended December 31, 2014.

The decrease was primarily related to the stock–based compensation expenses of $5.7 million in 2014 resulting mainly from immediately-vested granted stock options granted to board members and employees in the second half of 2014. In addition, professional fees increased due to additional legal fees after the Company became a public entity. The salary and related costs increased primarily due to new employees in the general and administrative department Patent filing expenses also increased due to the increase of worldwide patent certification activities.

General and administrative expense increased by $5.5 million to $7.5 million for the year ended December 31, 2014, compared to $2.0 million for the year ended December 31, 2013. The increase was primarily related to increases in expenses related to stock – based compensation of $5.7 million.

Other income

The following table summarizes other income (in thousands):

	Year Ended December 31,		
	2015	2014	2013
Interest income	$-	$1	$1
Other income	21	-	-
Foreign exchange gain	6	53	(3)
Total	$27	$54	$(2)

Other income consists primarily of a $21 thousand gain from the sale of fully-depreciated scientific equipment for the year ended December 31, 2015. Foreign exchange expense changed in the year ended December 31, 2015 compared to the year ended December 31, 2014. Also, the foreign exchange gain in the year ended December 31, 2014 due to the Euro and Canadian dollar exchange rate fluctuation, compared to the year ended December 31, 2013.

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, 2015, we have funded our operations principally through the private placement of equity securities and our initial public offering, which have provided aggregate cash proceeds of approximately $221.0 million. At December 31, 2015, we had cash and cash equivalents of $91.1 million as compared to cash and cash equivalents of $57.3 million at December 31, 2014. The following table summarizes our sources and uses of cash (in thousands):

	Year Ended December 31,		
Net cash (used in) provided by:	2015	2014	2013
Operating activities	$(33,308)	$(11,700)	$(8,908)
Investing activities	(10,392)	(1,397)	(59)
Financing activities	77,470	63,200	12,045
Effect of foreign exchange rate on cash and cash equivalents	(48)	(18)	(1)
Net change in cash and cash equivalents	$33,722	$50,085	$3,077

During the years ended December 31, 2015, 2014 and 2013, our operating activities used net cash of $33.3 million, $11.7 million and $8.9 million, respectively. The use of net cash in each of these periods primarily resulted from our net losses. The increase in net loss from operations for the year ended December 31, 2015 as compared to the year ended December 31, 2014 and 2013 was mainly due to the increase in clinical trial activities in Europe and the growing size of workforce.

During the years ended December 31, 2015, 2014 and 2013, our investing activities used net cash of $10.4 million, $1.4 million, and $0.01 million, respectively. We spent approximately $8.1 million on the construction of our new manufacturing facility and building during the year ended December 31, 2015, which was started in the beginning of 2015. We also spent $0.9 million more on purchases of scientific equipment during the year ended December 31, 2015, compared to $1.4 million during the year ended December 31, 2014.

During the years ended December 31, 2015, 2014 and 2013, our financing activities provided net cash proceeds of $77.5 million, $63.2 million and $12 million, respectively. During the year ended December 31, 2015, we received IPO proceeds of $76.0 million and incurred offering costs of $5.4million, which consisted of underwriters' commission direct incremental legal, accounting and other professional service fees related to our IPO. Also, during the year ended December 31, 2015, investors exercised warrants to purchase a total of 373,332 shares of our common stock at an exercise price of $15.00 per share for a total of approximately $5.6 million in net proceeds, and employees exercised stock option to purchase a total of 359,141 shares of our common stock for a total of approximately $1.3 million in net proceeds. In January 2015, we received previously outstanding subscription receivable in the amount of $0.4 million.

On April 14, 2015, our registration statement on Form S-1 (File No. 333-201813) was declared effective by the SEC for our initial public offering pursuant to which we sold an aggregate of 4,000,000 shares of our common stock at a price of $19.00 per share. The offering commenced as of April 14, 2015 and did not terminate before all of the securities registered in the registration statement were sold. On April 17, 2015, we closed the sale of such shares, resulting in net proceeds to us of approximately $70.6 million after deducting underwriting discounts and commissions of $3.8 million and other offering expenses of approximately $1.6 million. No payments were made by us to directors, officers or persons owning ten percent or more of our common stock or to their associates, or to our affiliates. There has been no material change in the planned use of proceeds from our initial public offering as described in our final prospectus filed with the Securities and Exchange Commission on April 16, 2015 pursuant to Rule 424(b).

We expect to continue to incur substantial operating losses in the future. We will not receive any product revenue until a drug candidate has been approved by the FDA or similar regulatory agencies in other countries and successfully commercialized. As of December 31, 2015, our principal sources of liquidity were our cash and cash equivalents, which totaled approximately $91.1 million.

Contractual Obligations and Commitments

On January 12, 2008, we entered a lease agreement to lease our facility in Austin, Texas. On September 15, 2010, we entered into a second lease agreement to lease additional space in Austin, Texas. On March 20, 2014, we extended the lease for an additional 21 months on the same terms and rental rates as the current lease. Rent expense was approximately $688,000, $535,000 and $553,000 for the years ended December 31, 2015, 2014 and 2013, respectively. On February 28, 2015, we extended the lease for another 4 years. The future minimum lease payments are as follows as of December 31, 2015 (in thousands):

Contractual Obligations	Total	Less than 1 Year	1 - 3 Years	3 - 5 Years	More than 5 Years
Operating facility leases	$1,458	$ 448	$ 931	$ 79	$ —
Total contractual obligations	$1,458	$ 448	$ 931	$ 79	$ —

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 DISCLOSURE OF MARKET RISKS

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

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of

XBiotech Inc.

We have audited the accompanying consolidated balance sheets of XBiotech Inc. (the Company) as of December 31, 2015 and 2014, and the related consolidated statements of operations, comprehensive loss, shareholders' equity and cash flows for each of the three years in the period ended December 31, 2015. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purposes of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of XBiotech Inc. at December 31, 2015 and 2014, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2015, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

Austin, Texas

March 30, 2016

XBiotech Inc.

Consolidated Balance Sheets

(in thousands, except share data)

	December 31, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$91,051	$57,329
Prepaid expenses and other current assets	1,990	411
Deferred offering costs	-	324
Total current assets	93,041	58,064
Property and equipment, net	5,946	3,227
Building construction in progress	10,371	886
Total assets	$109,358	$62,177
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	$4,825	$1,629
Accrued expenses	1,466	1,518
Total current liabilities	6,291	3,147
Long-term liabilities:		
Deferred rent	17	-
Total liabilities	6,308	3,147
Shareholders' equity:		
Preferred Stock, no par value, unlimited shares authorized, no shares outstanding	-	-
Common stock, no par value, unlimited shares authorized, 32,279,106 and 27,546,632 shares outstanding at December 31, 2015 and December 31, 2014, respectively	233,902	152,351
Accumulated other comprehensive loss	(201)	(153)
Accumulated deficit	(130,651)	(93,168)
Total shareholders' equity	103,050	59,030
Total liabilities and shareholders' equity	$109,358	$62,177

See accompanying notes.

XBiotech Inc.

Consolidated Statements of Operations

(in thousands, except share and per share data)

	Year Ended December 31,		
	2015	2014	2013
Operating expenses:			
Research and development	$31,310	$14,329	$7,935
General and administrative	6,200	7,449	1,990
Total operating expenses	37,510	21,778	9,925
Loss from operations	(37,510)	(21,778)	(9,925)
Other income (loss):			
Interest income	-	1	1
Other income	21	-	-
Foreign exchange gain (loss)	6	53	(3)
Total other income (loss)	27	54	(2)
Net loss	$(37,483)	$(21,724)	$(9,927)
Net loss per share—basic and diluted	$(1.22)	$(0.90)	$(0.45)
Shares used to compute basic and diluted net loss per share	30,801,994	24,162,700	22,220,416

See accompanying notes.

XBiotech Inc.

Consolidated Statements of Comprehensive Loss

(in thousands)

	Year Ended December 31,		
	2015	2014	2013
Net loss	$(37,483)	$(21,724)	$(9,927)
Foreign currency translation adjustment	(48)	(18)	(1)
Comprehensive loss	$(37,531)	$(21,742)	$(9,928)

See accompanying notes.

XBiotech Inc.

Consolidated Statements of Shareholders' Equity

(in thousands)

	Number of Shares	Common Stock Amount	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total
Balance at December 31, 2012	21,548	$68,284	$ (134)	$ (61,517)	$7,372
Net loss	-	-	-	(9,927)	(9,927)
Foreign currency translation adjustment	-	-	(1)	-	(1)
Issuance of common stock under stock option plan	1,205	12,045	-	-	12,045
Share-based compensation expense	-	1,478	-	-	739
Balance at December 31, 2013	22,752	81,807	(135)	(71,444)	10,228
Net loss	-	-	-	(21,724)	(21,724)
Foreign currency translation adjustment	-	-	(18)	-	(18)
Issuance of common stock, net of issuance cost	4,780	63,784	-	-	63,784
Issuance of common stock under stock option plan	15	150	-	-	150
Stock subscription receivable	-	(410)	-	-	(410)
Share-based compensation expense	-	7,020	-	-	7,020
Balance at December 31, 2014	27,547	152,351	(153)	(93,168)	59,030
Net loss	-	-	-	(37,483)	(37,483)
Foreign currency translation adjustment	-	-	(48)	-	(48)
Issuance of common stock, net of issuance cost	4,373	75,386	-	-	75,386
Issuance of common stock under stock option plan	359	1,348	-	-	1,348
Collection of stock subscription receivable	-	410	-	-	410
Share-based compensation expense	-	4,407	-	-	4,407
Balance at December 31, 2015	32,279	$233,902	$ (201)	$ (130,651)	$103,050

See accompanying notes.

XBiotech Inc.

Consolidated Statements of Cash Flows

(in thousands)

	Year Ended December 31,		
	2015	2014	2013
Operating activities			
Net loss	$(37,483)	$(21,724)	$(9,927)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	699	664	784
Share-based compensation expense	4,407	7,020	739
Gain on disposal of property and equipment	(157)	-	-
Changes in operating assets and liabilities:			
Prepaid expenses and other current	(1,579)	38	(252)
Accounts payable	840	1,068	103
Accrued expenses	(52)	1,234	(326)
Deferred rent	17	-	(29)
Net cash used in operating activities	(33,308)	(11,700)	(8,908)
Investing activities			
Purchase of property and equipment	(2,322)	(1,397)	(59)
Expenditures on building construction	(8,070)	-	-
Net cash used in investing activities	(10,392)	(1,397)	(59)
Financing activities			
Issuance of common stock and warrants, net	75,712	63,784	12,045
Issuance of common stock under stock option plan	1,348	150	-
Collection of subscription receivable	410	-	-
Deferred offering costs	-	(324)	-
Net cash provided by financing activities	77,470	63,200	12,045
Effect of foreign exchange rate on cash and cash equivalents	(48)	(18)	(1)
Net change in cash and cash equivalents	33,722	50,085	3,077
Cash and cash equivalents, beginning of period	57,329	7,244	4,167
Cash and cash equivalents, end of period	$91,051	$57,329	$7,244

See accompanying notes.

XBiotech Inc.

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 Schweiz AG, a wholly-owned subsidiary of the Company, was incorporated in Zug, Switzerland in August 2010. XBiotech Japan KK, a wholly-owned subsidiary of the Company, was incorporated in Tokyo, Japan in March 2013. XBiotech GmbH, a wholly-owned subsidiary of the Company, was incorporated in Germany in January 2014.

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.

In 2005, the Company began to develop a new framework for commercial manufacturing, using technology that required less capital, fewer operators and provided greater flexibility than standard industry practices.

With the manufacturing capability to produce its True Human™ antibody therapy, in 2010 the Company began a clinical trial program. The first clinical trial program at MD Anderson Cancer Center began treating the sickest cancer patients irrespective of tumor type. Soon thereafter, the Company used the same antibody therapy in various clinical studies at treatment centers around the United States (U.S.) and abroad to investigate the antibody effect in patients that had vascular disease, leukemia, type 2 diabetes, psoriasis or acne.

The Company’s headquarters are located in Austin, Texas.

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 $91.0 million at December 31, 2015, will enable the Company to maintain its current and planned operations for the foreseeable future.

2. Significant Accounting Policies

Basis of Presentation

These consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States, or US GAAP.

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 United States 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.

Prior to its initial public offering on April 15, 2015, the Company utilized significant estimates and assumptions in determining the fair value of its common stock. The board of directors determined the estimated fair value of the Company’s common stock based on a number of objective and subjective factors, including the prices at which the Company sold shares of its common stock to third parties and external market conditions affecting the biotechnology industry sector.

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.

Income Taxes

The Company makes estimates and judgments in determining the need for a provision for income taxes, including the estimation of its taxable income or loss for the full fiscal year. The Company has accumulated significant deferred tax assets that reflect the tax effects of net operating losses and tax credit carryovers and temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Realization of certain deferred tax assets is dependent upon future earnings. The Company is uncertain about the timing and amount of any future earnings. Accordingly, the Company offsets these deferred tax assets with a valuation allowance. The Company may in the future determine that certain deferred tax assets will likely be realized, in which case the Company will reduce its valuation allowance in the period in which such determination is made. If the valuation allowance is reduced, the Company may recognize a benefit from income taxes in its statement of operations in that period.

Share-Based Compensation

The Company accounts for its share-based compensation awards in accordance with ASC Topic 718, *Compensation-Stock Compensation* (“ASC 718”). ASC 718 requires all share-based payments to employees, including grants of employee stock options, to be recognized in the statements of operations based on their grant date fair values. For stock options granted to employees and to members of the board of directors for their services on the board of directors, the Company estimates the grant date fair value of each option award using the Black-Scholes option-pricing model. The use of the Black-Scholes option-pricing model requires management to make assumptions with respect to the expected life of the option and 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. 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.

Share-based compensation expense recognized for the years ended December 31, 2015, 2014 and 2013 was included in the following line items on the Consolidated Statements of Operations (in thousands).

	Year Ended December 31,		
	2015	2014	2013
Research and development	$2,204	$1,303	$551
General and administrative	2,203	5,717	188
Total share-based compensation expense	$4,407	$7,020	$739

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No related tax benefits were recognized for the years ended December 31, 2015, 2014 and 2013.

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,								
	2015			2014			2013		
Weighted-average grant date fair value per share	$17.95			$8.23			$11.37		
Expected volatility	66%	–	71%	70%	–	73%	73%		
Risk-free interest rate	1.07%	–	2.42%	0.69%	–	2.73%	2.04%	–	3.84%
Expected life (in years)	3	–	10	3	–	10	6.25	–	10
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, Swiss 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 Company follows ASC Topic 820, *Fair Value Measurements and Disclosures*, which establishes a fair value hierarchy for those instruments measured at fair value that distinguishes between assumptions based on market data (observable inputs) and the Company's own assumptions (unobservable inputs). The hierarchy consists of three levels:

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

At December 31, 2015 and 2014, the Company did not have any assets or liabilities that were remeasured at fair value on a recurring basis. The carrying amounts reflected in the balance sheets for cash and cash equivalents, prepaid expenses and other current assets, accounts payable, and accrued expenses approximate their fair values at December 31, 2015and 2014, due to their short-term nature.

Property and Equipment

Property and equipment, which consists of land, furniture and fixtures, computers and office equipment, scientific equipment, leasehold improvements and vehicles are stated at cost and depreciated over the estimated useful lives of the assets, with the exception of land which is not depreciated, using the straight line method. The useful lives are as follows:

- Furniture and fixtures 7 years
- Office equipment 5 years
- Leasehold improvements Shorter of asset's useful life or remaining lease term
- Scientific equipment 5 years
- Vehicles 5 years

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.

Building Construction in Progress

Building construction in progress consists of the accumulated expenditures to build the new XBiotech manufacturing facility located in Austin, Texas, which includes the cost for land clearing, architecture design, engineering services, city permits, installation of utilities, construction materials and labor and construction management. Once the building is completed and placed into service, the Company will commence depreciation over its estimated useful life.

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, 2015.

Deferred Offering Costs

Deferred offering costs, which consist of direct incremental legal, accounting and other professional service fees relating to the Company's initial public offering (IPO) were capitalized. The deferred offering costs were offset against the proceeds from the IPO in April 2015.

Foreign Currency Transactions

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

of a foreign currency transaction in determining net loss for the period in which the transaction is settled.

Comprehensive Income (Loss)

ASC Topic 220, *Comprehensive Income*, requires that all components of comprehensive income (loss), including net income (loss), be reported in the financial statements in the period in which they are recognized. Comprehensive income (loss) is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources, including unrealized gains and losses on investments and foreign currency translation adjustments.

Segment and Geographic Information

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker, or decision making group, in making decisions on how to allocate resources and assess performance. The Company's chief operating decision maker is the Chief Executive Officer. The Company and the chief operating decision maker view the Company's operations and manage its business as one operating segment. Substantially all of the Company's operations are in the U.S. geographic segment.

Net Loss per Share

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

Subsequent Events

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

Recent Accounting Pronouncements

In June 2014 the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update 2014-10, *Elimination of Certain Financial Reporting Requirements, including an Amendment to Variable Interest Entities Guidance in Topic 810 Consolidation*. These updates remove the definition of a development stage entity from the Master Glossary of the ASC, thereby removing the financial reporting distinction between development stage entities and other reporting entities from U.S. GAAP. In addition, the amendments eliminate the requirements for development stage entities to (1) present inception-to-date information in the statements of income, cash flows, and shareholder equity, (2) label the financial statements as those of a development stage entity, (3) disclose a description of the development stage activities in which the entity is engaged, and (4) disclose in the first year in which the entity is no longer a development stage entity that in prior years it had been in the development stage. This standard is effective for annual reporting periods beginning after December 15, 2014. The Company has early adopted this standard in the presentation of its financial statements.

In August 2014 the FASB issued ASU 2014-15*, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*. The ASU is intended to define management's responsibility to evaluate whether there is substantial doubt about an organization's ability to continue as a going concern and to provide related footnote disclosures. For all entities, the ASU is effective for annual periods ending after December 15, 2016 and interim periods within annual periods beginning after December 15, 2016.

In February 2016 the FASB issued final guidance that will change the accounting for leases. The FASB issued final guidance that requires lessees to put most leases on their balance sheets but recognize expenses on their income statements in a manner similar to today's accounting. The guidance also eliminates today's real estate-specific provisions for all entities. For lessors, the guidance modifies the classification criteria and the accounting for sales-type and direct financing leases. All entities classify leases to determine how to recognize lease-related revenue and expense. Classification continues to affect what lessors record on the balance sheet. For calendar-year public business entities and certain calendar-year not-for-profit entities and employee benefit plans, the guidance is effective in 2019, and interim periods within that year. For other calendar-year entities, it is effective in 2020, and interim

periods in 2021. Early adoption is permitted for all entities.

3. Property and Equipment

Property and equipment consisted of the following as of December 31, 2015 and 2014 (in thousands):

	2015	2014
Computer and office equipment	$335	$262
Furniture and fixtures	132	126
Land	1,418	1,418
Leasehold improvements	770	762
Scientific equipment	5,595	4,648
Vehicle	30	30
Construction in process	2,417	189
Building Construction in process	10,371	885
Accumulated depreciation	(4,751)	(4,207)
	$16,317	$4,113

Depreciation expenses related to property and equipment amounted to approximately $699,000, $644,000, and $784,000 and for the years ended December 31, 2015, 2014 and 2013, respectively. Construction in process is related to R&D and manufactory equipment.

4. Accrued Expenses

Accrued expenses consist of the following as of December 31, 2015, and 2014 (in thousands):

	2015	2014
Accrued compensation and related	$319	$1,037
Accrued professional fees	119	134
Accrued clinical trial	278	183
Other	628	164
	$1,344	$1,518

5. Common Stock

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

In August 2013, we sold 1.2 million shares of common stock at a price of $10.00 per share for total proceeds of approximately $12.0 million. Each share had one warrant attached, exercisable for 180 days into a single common share in the Company at a price of $10.00 per share.

In February 2014, the Company sold 1.2 million shares of common stock for total proceeds of approximately $12.0 million from the exercise of warrants by its warrant holders. From July through November 18, 2014, the Company sold approximately 601,000 shares of common stock at a price of $15.00 per share for total proceeds of approximately $9.0 million. Each share had one warrant attached, which would be exercisable for 180 days into a single common share in the Company at a price of $15.00 per share. As of December 31, 2014, the Company had total warrants

outstanding for the purchase of 493,000 shares of common stock at a price of $15.00 per share.

From November 24, 2014 through December 31, 2014, the Company sold 3.0 million shares of common stock at $15.00 per share pursuant to stock subscription agreements for total proceeds of $44.8 million of which $410,000 remained uncollected as of December 31, 2014 and was received in January 2015. The Company incurred issuance costs of approximately $1.9 million in cash and $0.4 million in non-cash consideration.

In December 2014, 15,000 stock options were exercised at a price of $10.00 for total proceeds of $0.15 million.

From January to March 2015, warrants to purchase a total of 164,999 shares of common stock were exercised at $15.00 per share for a total of $2.5 million. Also, the Company received approximately $8,000 in January 2015 from 15,000 exercised stock options at $0.55 per share.

On April 17, 2015, the Company sold 4.0 million shares of common stock at $19.00 per share in its Initial Public Offering (“IPO”) resulting in net proceeds of $70.6 million.

From April to June 2015, excluding the IPO, the Company issues 208,333 shares of common stock for total proceeds of approximately $3.1 million from the exercise of warrants by common stock shareholders. Also, the Company received $0.7 million from 106,000 exercised stock options.

In July 2015, 12,000 stock options were exercised at a price of $2.50 for total proceeds of $30,000.

From October through December 31, 2015, 226,141 shares of common stock were issued upon the exercise of stock option at the price $ 0.53 to $10 per share for a total of $639,253.

6. Common Stock Options

On November 11, 2005, the board of directors of the Company adopted a stock option plan (“the 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 will be non-transferable and may be exercised only by the participant, or in the event of the death of the participant, a legal representative until the earlier of the options’ expiry date or the first anniversary of the participant’s death, or such other date as may be specified by the Compensation Committee.

The term of the options is at the discretion of the Compensation Committee, but may not exceed 10 years from the grant date. The options expire on the earlier of the expiration date or the date three months following the day on which the participant ceases to be a director, 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.

The number of common shares reserved for issuance to any one person pursuant to this 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 Plan is as follows:

	Options	Exercise Price	Weighted-Average Exercise Price
Options outstanding at December 31, 2012	3,669,666	$0.60 – $15.00	$ 7.01
Granted	40,000	15.00	15.00
Exercised	–		
Forfeitures	(316,167)	2.50 – 15.00	8.39
Options outstanding at December 31, 2013	3,393,499	0.60 – 15.00	6.02
Granted	1,563,666	1.00 – 15.00	11.23
Exercised	(15,000)	10.00	10.00
Forfeitures	(58,000)	2.50 – 15.00	10.63

Options outstanding at December 31, 2014	4,884,165	$0.55 -	$15.00	7.03
Granted	375,928	8.47 -	21.99	17.95
Exercised	(359,141)	0.53 -	10.00	3.75
Forfeitures	(114,375)	0.55 -	20.93	11.05
Options outstanding at December 31, 2015	4,786,577	$0.53 -	$21.99	$ 8.56

The weighted average fair value of the options issued to directors, employees and consultants during the fiscal years ended December 31, 2015, 2014 and 2013, was $17.95, $8.23 and $11.37, respectively. Options with an intrinsic value of $2.86, $2.90 and $2.51, became vested during 2015, 2014 and 2013, respectively. The total intrinsic value of options exercisable and total options outstanding at December 31, 2015 was $18,697,000 and $19,044,000, respectively. The total fair value of options vested during the years ended December 31, 2015, 2014 and 2013 was $$5,463,000, $6,999,000 and $632,500, respectively.

As of December 31, 2015, there was approximately $5.0 million of unrecognized compensation cost, related to stock options granted under the Plan which will be amortized to stock compensation expense over the next 2.02 years.

The following table summarizes information concerning outstanding options under the Plan as of December 31, 2015:

	Options outstanding			Options Vested and Outstanding	
Exercise Price	Number	Weighted-Average Remaining Contractual Life	Weighted-Average Exercise Price	Number	Weighted-Average Exercise Price
$ 0.50	15,000	0.22	$ 0.50	15,000	$ 0.50
$ 0.72	20,000	0.95	$ 0.72	20,000	$ 0.72
$ 0.90	255,000	1.44	$ 0.90	255,000	$ 0.90
$ 2.50	632,559	2.81	$ 2.50	619,559	$ 2.50
$ 3.75	1,000,000	4.29	$ 3.75	1,000,000	$ 3.75
$ 5.00	77,700	4.57	$ 5.00	77,700	$ 5.00
$ 7.00	1,000	5.17	$ 7.00	1,000	$ 7.00
$ 7.50	701,999	5.30	$ 7.50	701,999	$ 7.50
$ 8.47	4,500	0.92	$ 8.47	0	$ 8.47
$ 10.00	1,025,433	7.18	$ 10.00	640,308	$ 10.00
$ 14.18	21,000	9.84	$ 14.18	0	$ 14.18
$ 15.00	778,458	7.81	$ 15.00	656,333	$ 15.00
$ 16.91	65,900	9.74	$ 16.91	0	$ 16.91
$ 18.02	15,660	9.48	$ 18.02	15,660	$ 18.02
$ 19.00	22,500	9.26	$ 19.00	0	$ 19.00
$ 19.09	49,000	9.36	$ 19.09	32,000	$ 19.09
$ 19.94	6,000	9.36	$ 19.94	0	$ 19.94
$ 20.11	9,000	9.48	$ 20.11	0	$ 20.11
$ 20.49	4,500	9.48	$ 20.49	0	$ 20.49
$ 20.93	70,368	9.48	$ 20.93	0	$ 20.93
$ 21.99	9,000	9.46	$ 21.99	0	$ 21.99
	4,784,577	5.56	8.01	4,114,857	6.89

7. Net Loss Per Share

The following summarizes the computation of basic and diluted net loss per share for the years ended December 31, 2015, 2014 and 2013 (in thousands, except share and per share data):

	Year Ended December 31,		
	2015	2014	2013
Net loss	$(37,483)	$(21,724)	$(9,927)
Weighted-average number of common shares—basic and diluted	30,801,994	24,162,700	22,220,416
Net loss per share—basic and diluted	$(1.22)	$(0.90)	$(0.45)

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

	Year Ended December 31,		
	2015	2014	2013
Stock options	4,786,577	4,884,165	3,393,499
Warrants to purchase common stock	-	493,000	1,204,510
Total	4,786,577	5,377,165	4,598,009

8. Income Taxes

The Company recorded no provision for income taxes for the years ended December 31, 2015, 2014 and 2013 due to the reported net losses in each year.

A reconciliation of the Company’s Canadian federal statutory income tax rate to the Company’s effective income tax rate is as follows for the years ended December 31, 2015, 2014 and 2013:

	2015	2014	2013
Income tax benefit computed at federal tax rate	26.0 %	26 %	13.50%
Change in valuation allowance	(27.2%)	(18%)	(10 %)
Stock compensation and other	1.2 %	(8 %)	(3.5 %)
Total	— %	— %	— %

During the years ended December 31, 2015, 2014 and 2013, the Company had no interest and penalties related to income taxes.

As of December 31, 2015, and 2014, the Company has unused net operating losses of approximately $87.1 million .(approximately $70.8 million in Canada, $11.7 million in the U.S., $4.0 million in Germany and $0.6 million in Switzerland and Japan) and $62.6 million (approximately $51.2 million in Canada, $9.7 million in the U.S., $1.1 million in Germany and $0.6 million in Switzerland and Japan) respectively available to reduce taxable income of future years. The net operating losses begin to expire in 2018.

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amount of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The Company has established a valuation allowance due to uncertainties regarding the realization of deferred tax assets based upon the Company's lack of earnings history. Significant components of the Company's deferred tax assets and liabilities as of December 31, 2015, 2014 and 2013 as follows (in thousands):

	2015	2014	2013
Deferred tax assets:			
Noncapital losses	$23,038	$16,901	8,820
Qualifying research and development credits	1,591	1,311	878
Stock based compensation	3,982	312	—
Share issue costs	30	4	—
Accrued liabilities	356	160	—
Deferred Rent	6	—	—
Depreciation	—	—	68
Total deferred tax assets	29,003	18,688	9,766
Deferred tax liabilities:			
Stock Option Exercised			
Depreciation	13	40	—
Accrued liabilities	—	—	74
Share issuance costs	23	—	431
Total deferred tax liabilities	36	40	505
Net deferred tax asset	28,967	18,648	9,261
Valuation allowance for deferred tax assets	(28,967)	(18,648)	(9,261)
Net deferred tax asset including valuation allowance	$—	$—	$—

The valuation allowance increased by approximately $10.3 and $9.4 million during the year ended December 31, 2015 and 2014 respectively.

The Company applies the accounting guidance in ASC 740 related to accounting for uncertainty in income taxes. The Company's reserves related to taxes are based on a determination of whether, and how much of, a tax benefit taken by the Company in its tax filings or positions is more likely than not to be realized following resolution of any potential contingencies present related to the tax benefit. As of December 31, 2015 and 2014, the Company had no unrecognized tax benefits.

The Company files federal income tax returns in Canada, US, Switzerland, Germany, and Japan. The Company also files income tax returns in the state of Texas in the US. The statute of limitations for assessment by local taxing authorities is open for tax years ended after December 2011. There are currently no federal or state income tax audits in progress.

9. Related-Party Transactions

Legal fees of approximately $37,000 and $35,000 were incurred to a law firm for legal services rendered in which a former director of the Company is a senior partner in 2014 and 2013, respectively. The Company had outstanding accounts payable to the same firm in the amount of approximately $37,000 at December 31, 2014. No outstanding account payable to such law firm as of December 31, 2013. There are no related-party transactions in 2015.

10. Commitments and Contingencies

On January 12, 2008, the Company entered a lease agreement to lease its facility in Austin, Texas, U.S. On September 15, 2010, the Company entered into a second lease agreement to lease additional space in Austin, TX, U.S. Both leases expired in 2013. On March 20, 2013, the company extended the lease for another 21 months with the same terms and rental rates as the current leases. On February 28, 2015, the Company extended the leases for another four years with two years early termination right. Rent expense was approximately $688,000, $535,000 and $553,000 for the years ended December 31, 2015, 2014 and 2013, respectively. The future minimum lease payments are as follows as of December 31, 2015 (in thousands):

2016	$448
2017	$460
2018	$471
2019	$79

XBiotech Corporate officers, Queena Han (VP of Finance) and John Simard (President and CEO), along with XBiotech Inc. were named defendants in securities class action civil suits filed in federal court at the U.S. District Court for the Western District of Texas, in Austin, Texas and state court at the Los Angeles County Superior Court, in California. In the California action, the underwriter WR Hambrecht & Co., LLC is also named as a defendant. These civil suits were filed on December 1, 2015. The foundation for both suits are similar in that the plaintiffs allege the officers of the company made false and misleading statements, violating the securities laws, in the IPO documents in April 2015. Specifically, these alleged false statements in the IPO documents are in relation to the European Phase III clinical trial for Xilonix™. The allegations focus on a press release posted by XBiotech on November 23, 2015 explaining certain issues with patient data. Plaintiffs allege the company knew of these issues during the IPO and neglected to disclose them in supporting documentation filed with the SEC. As a result of the news release, XBiotech (traded on the Nasdaq) stock tumbled. The resulting securities class action lawsuits are seeking relief for plaintiffs who report financial losses due to the alleged false and misleading statements. Both lawsuits are in the early procedural stages. As of February 2016, a lead plaintiff was assigned in the Texas case with the amended complaint scheduled to be filed with the court in April 2016. In California, motions to challenge venue and personal jurisdiction are due, by defendants, to the court in May 2016.

Financial Statement Schedules

None

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.

No change in the Company's internal controls over financial reporting (as defined in Rule 13a-15(f) and 15d-15(f) of the Exchange Act) occurred during the Company's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Management's Annual Report on Internal Control over Financial Reporting

Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our internal control over financial reporting is designed 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 in the United States. This process includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures are being made only in accordance with authorizations of our management and directors; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of the internal control over financial reporting to future periods are subject to risk that the internal control may become inadequate because of changes in conditions, or that the degree of compliance with policies or procedures may deteriorate.

Management's Assessment of the Effectiveness of our Internal Control over Financial Reporting

The Company's management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act). Management conducted an assessment of the effectiveness of the Company's 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 the Company's assessment, management has concluded that its internal control over financial reporting was effective as of December 31, 2015 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, 2015 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.

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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, Governance and Review Committee” and “Audit Committee,” contained in our definitive Proxy Statement (the “Proxy Statement”), which we will file on or about April 29, 2016 with the Securities and Exchange Commission in connection with the solicitation of proxies for our 2016 Annual Meeting of Stockholders to be held on June 20, 2016.

ITEM 11. EXECUTIVE COMPENSATION

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

ITEM 12. SECURITY OWNERSHIP OF CERTATIN 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 RELATIONSHPS AND RELATED TRANSACTIONS AND DIRECTOR INDENPENDENCE

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 ACCOUNTING 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

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 30, 2016.

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 30, 2016
/S/ QUEENA HAN Queena Han, Vice President of Finance & Human Resources (Principal Financial Officer and Principal Accounting Officer)	March 30, 2016
/S/ FABRIZIO BONANNI Fabrizio Bonanni, Director	March 30, 2016
/S/ W. THORPE MCKENZIE W. Thorpe McKenzie, Director	March 30, 2016
/S/ DANIEL VASELLA Daniel Vasella, Director	March 30, 2016

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EXHIBIT INDEX

Exhibit Number	Description
3.1	Certificate of Continuation dated September 23, 2005, issued by the Registrar of Companies, Province of British Columbia, Canada (incorporated by reference to Exhibit 3.1 to the Company's Registration Statement on Form S-1 filed with the SEC on February 2, 2015)
3.2	Notice of Articles, dated December 8, 2005, issued by the Registrar of Companies, Province of British Columbia, Canada (incorporated by reference to Exhibit 3.1 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 3.1 to the Company's Registration Statement on Form S-1 filed with the SEC on February 2, 2015)
10.1+	Executive Employment Agreement dated as of March 22, 2005 between XBiotech and John Simard (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)
10.2+	Change in Control Agreement dated as of March 22, 2005 between XBiotech and John Simard(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)
10.3	Confidentiality and Assignment of Inventions Agreement dated as of March 22, 2005 between XBiotech and John Simard (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)
10.4+	XBiotech 2005 Incentive Stock Option Plan (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)
10.5+	Form of indemnification agreement between XBiotech and each director of XBiotech(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)
10.6	Agreement of Lease by and between NNN Met Center 4-9, LP and XBiotech USA, Inc. dated January 14, 2008 and the First Amendment dated January 17, 2008, the Second Amendment dated August 2010 and the Third Amendment dated March 2013 and the Forth Amendment dated February 28, 2015 (incorporated by reference to Exhibit 3.1 to the Company's Registration Statement on Form S-1 filed with the SEC on March 10, 2015)
10.7	Agreement of Lease by and between NNN Met Center 4-9, LLP and XBiotech USA, Inc. for Suite 600 dated August 16, 2010 and First Amendment dated March 2013 and the Second Amendment dated February 28, 2015 (incorporated by reference to Exhibit 3.1 to the Company's Registration Statement on Form S-1 filed with the SEC on March 10, 2015)
10.8+	Board Member Agreement dated November 4, 2014 between XBiotech, Inc. and Daniel Vasella (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)

10.9	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 3.1 to the Company's Registration Statement on Form S-1 filed with the SEC on March 10, 2015)
10.10	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 3.1 to the Company's Registration Statement on Form S-1 filed with the SEC on March 10, 2015)
10.11	XBiotech Inc. 2015 Equity Incentive Plan (incorporated by reference to Exhibit 3.1 to the Company's Registration Statement on Form S-1 filed with the SEC on March 10, 2015)
21.1*	List of subsidiaries
23.1*	Consent of 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
31.1*	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
31.2*	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
101	The following financial statements from the Xbiotech, Inc. Annual Report on Form 10-K for the year ended December 31, 2015, formatted in Extensive Business Reporting Language (XBRL): (i) consolidated balance sheets, (ii) consolidated statements of operations, (iii) consolidated statements of stockholders' equity, (iv) consolidated statements of cash flows, and (v) notes to consolidated financial statements (detail tagged).

\+ Indicates management contract or compensatory plan
* Filed herewith