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UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, DC 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, 2017

☐ **TRANSITION REPORTS PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.**
For the transition period from to

Commission File Number: 001-37937

XENETIC BIOSCIENCES, INC.
(Exact name of registrant as specified in its charter)

Nevada	**45-2952962**
(State or other jurisdiction of incorporation or organization)	**(IRS Employer Identification No.)**

99 Hayden Ave, Suite 230
Lexington, Massachusetts 02421
(Address of principal executive offices and zip code)

781-778-7720
(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, $0.001 par value per share	The NASDAQ Stock Market LLC

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) 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: Yes ☐ No ☒

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. (Check one):

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☒
(Do not check if a smaller reporting company)			

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

The aggregate market value of the common stock held by non-affiliates of the registrant as of June 30, 2017, based upon the closing price of the registrant's common stock on the NASDAQ Capital Market on that date of $2.76, was approximately $9,047,647. For purposes of this computation, all officers, directors, and 10% beneficial owners of the registrant are deemed to be affiliates. Such determination should not be deemed to be an admission that such officers, directors or 10% beneficial owners are, in fact, affiliates of the registrant.

As of March 16, 2018, the number of outstanding shares of the registrant's common stock was 8,717,541.

DOCUMENTS INCORPORATED BY REFERENCE

Information required in response to Part III of Form 10-K (Items 10, 11, 12, 13 and 14) is hereby incorporated by reference to portions of the registrant's definitive proxy statement or information statement for its 2017 Annual Meeting of Stockholders. The registrant intends to file a definitive proxy statement or information statement with the Securities and Exchange Commission no later than 120 days after the end of the registrant's fiscal year ended December 31, 2017.

XENETIC BIOSCIENCES, INC.
2017 ANNUAL REPORT ON FORM 10-K

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K ("Annual Report") contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 27A of the Securities Act of 1933, as amended. All statements contained in this Annual Report other than statements of historical fact, including statements regarding our future results of operations and financial position, our business strategy and plans, future revenues, projected costs, prospects and our objectives for future operations, are forward-looking statements. These forward-looking statements include, but are not limited to, statements concerning our plans to continue the development of our proposed drug candidate; our expectations regarding the nature, timing and extent of clinical trials and proposed clinical trials; our expectations regarding the timing for proposed submissions of regulatory filings, including but not limited to any Investigational New Drug ("IND") filing or any New Drug Application ("NDA"); the nature, timing and extent of collaboration arrangements; the expected results pursuant to collaboration arrangements including the receipts of future payments that may arise pursuant to collaboration arrangements; the outcome of our plans to obtain regulatory approval of our drug candidates; the outcome of our plans for the commercialization of our drug candidates; our plans to address certain markets, engage third party manufacturers, and evaluate additional drug candidates for subsequent commercial development, and the likelihood and extent of competition to our drug candidates.

In some cases, these statements may be identified by terminology such as "may," "will," "should," "expect," "plan," "anticipate," "believe," "estimate," "predict," "potential," or "continue," or the negative of such terms and other comparable terminology. Although we believe that the expectations reflected in the forward-looking statements contained herein are reasonable, we cannot guarantee future results, the levels of activity, performance or achievements. These statements involve known and unknown risks and uncertainties that may cause our or our industry's results, levels of activity, performance or achievements to be materially different from those expressed or implied by forward-looking statements.

Such factors include, among others, the following factors that could cause actual results to differ materially include without limitation:

- our need to raise additional working capital for the purpose of further developing our primary drug candidate and to continue as a going concern;
- our ability to finance our business;
- our ability to successfully commercialize our current and future drug candidates;
- our ability to achieve milestone and other payments associated with our co-development collaborations and strategic arrangements;
- the impact of new technologies on our drug candidates and our competition;
- changes in laws or regulations of governmental agencies;
- interruptions or cancellation of existing contracts;
- impact of competitive products and pricing;
- product demand and market acceptance and risks;
- the presence of competitors with greater financial resources;
- product development and commercialization risks;
- continued availability of supplies or materials used in manufacturing at the current prices;
- the ability of management to execute plans and motivate personnel in the execution of those plans;
- our ability to attract and retain key personnel;
- adverse publicity related to our products or the Company itself;
- adverse claims relating to our intellectual property;

- the adoption of new, or changes in, accounting principles;
- the costs inherent with complying with statutes and regulations applicable to public reporting companies, such as the Sarbanes-Oxley Act of 2002;
- other new lines of business that the Company may enter in the future; and
- other factors set forth in the "Risk Factors" section of this Annual Report on Form 10-K and in subsequent filings we make with the Securities and Exchange Commission.

These factors are not necessarily all of the important factors that could cause actual results to differ materially from those expressed in the forward-looking statements in this Annual Report. Other unknown or unpredictable factors also could have material adverse effects on our future results. The forward-looking statements in this Annual Report are made only as of the date of this Annual Report, and we do not undertake any obligation to publicly update any forward-looking statements to reflect subsequent events or circumstances, except as required by law.

As used in this Annual Report, unless otherwise indicated, all references herein to “Xenetic,” the “Company,” “we” or “us” refer to Xenetic Biosciences, Inc. and its wholly owned subsidiaries.

Our brand and product names, including but not limited to Virexxa®, OncoHist™, PolyXen™, ErepoXen™, ImuXen™, and PulmoXen™. contained in this Annual Report are trademarks, registered trademarks or service marks of Xenetic Biosciences, Inc. and/or its subsidiaries in the United States of America (“USA” or “U.S.”) and certain other countries. All other company and product names may be trademarks of the respective companies with which they are associated.

PART I

ITEM 1 – BUSINESS

Overview

We are a clinical-stage biopharmaceutical company focused on the discovery, research and development of next-generation biologic drugs and novel oncology therapeutics. Our lead investigational product candidate is oncology therapeutic XBIO-101 ('sodium cridanimod') for the treatment of progestin - resistant endometrial cancer. We have exclusive rights to develop and commercialize XBIO-101 worldwide, except for specified countries in the Commonwealth of Independent States ("CIS"), including Russia. XBIO-101 has been granted orphan drug designation by the U.S. Food and Drug Administration ("FDA") for the potential treatment of progesterone receptor negative ("PrR-") endometrial cancer in conjunction with progesterone therapy. We are currently conducting a Phase 2 trial for XBIO-101, with the first patient dosed in October 2017, and expect to generate preliminary data from this trial before the end of 2018.

We have an extensive patent portfolio of over 170 issued patents and over 40 pending patent applications in the United States and worldwide, covering various aspects of our PolyXen™ platform technology and advanced polymer conjugate technologies, as well as our proprietary biologic drugs and novel oncology drug candidates. We believe our portfolio positions us well for strategic partnership and commercialization opportunities. Our objective is to maximize opportunities to out-license assets from our portfolio in order to generate working capital to both build long-term stockholder value and provide us with the funding necessary for clinical development of our oncology drug candidates through market launch.

We incorporate our patented and proprietary technologies into a number of drug candidates currently under development either in-house or with biotechnology and pharmaceutical industry collaborators to create what we believe will be next-generation biologic drugs with improved pharmacological properties over existing therapeutics. While we primarily focus on researching and developing oncology drugs, we also have significant interests in drugs being developed by our collaborators to treat other conditions.

Our lead proprietary technology is PolyXen, an enabling platform technology which can be applied to protein or peptide therapeutics. PolyXen employs the natural polymer polysialic acid ("PSA") to prolong a drug's circulating half-life and potentially improve other pharmacological properties. PolyXen has been demonstrated in human clinical trials to confer prolonged half-life on biotherapeutics such as recombinant human erythropoietin ("rhEPO") and recombinant Factor VIII ("rFVIII"). We believe this technology may be applied to a variety of drug candidates to enhance the properties of the therapeutic, potentially providing advantages over competing products.

Our drug candidates have resulted from our research activities or that of our collaborators and are in the development stage. As a result, we commit significant resources to our research and development activities and anticipate continuing to do so for the near future. To date, none of our drug candidates have received regulatory marketing authorization in the U.S. by the FDA nor in any other territories by any applicable agencies. Although we hold a broad patent portfolio, because of capital constraints the focus of our internal development efforts is currently limited to research and development of our lead product candidate XBIO-101.

We were incorporated under the laws of the State of Nevada in August 2011. We, directly or indirectly, through our wholly-owned subsidiary, Xenetic U.K., and its wholly-owned subsidiaries, Lipoxen, Xenetic Technologies, Inc. and SymbioTec, GmbH, own various U.S. federal trademark registrations and applications, and unregistered trademarks and service marks, including but not limited to Virexxa®, OncoHist™, PolyXen™, ErepoXen™, ImuXen™, and PulmoXen™.

Our Strategy

Our strategy is to develop oncology drug candidates through regulatory approval and commercialization, and to pursue a continuous and ongoing out-licensing effort for our PolyXen platform technology to drive incremental shareholder value and generate working capital to assist in providing the funding required to support our drug development efforts.

We intend to pursue orphan drug designations for relevant oncology indications as appropriate in both the U.S. and Europe. If our orphan oncology drug candidates are granted orphan drug designation, then we may benefit from certain key advantages of orphan status including market exclusivity.

We intend to advance our PolyXen platform technology by entering into collaborative out-license arrangements with global pharmaceutical companies who could apply the necessary resources for advancing drug candidates through to worldwide commercialization, or by entering into arrangements with other partners that would in-license our technology on a restrictive-market basis. The latter arrangement would provide support in the form of access to partner-generated clinical data which is informative when contemplating potential monetization of our proprietary technology in larger markets.

We intend to advance development of our drug candidates through a combination of our own in-house research and the use of contract manufacturing and contract research organizations in order to efficiently manage our resources. Continuous pipeline growth and advancement of out-licensed drug candidates is dependent, in part, on our ability to raise sufficient capital and to advance our existing co-development collaborations and strategic arrangements as well as enter into new such arrangements.

Recent Developments

Termination by Shire plc of further development of SHP656

In May 2017, we announced that our strategic collaborator, Shire plc ("Shire"), had terminated further development of SHP656, its polysialylated rFVIII drug candidate being developed using our proprietary PolyXen technology. While Shire's Phase 1/2 trial demonstrated SHP656's efficacy and pharmacokinetic data commensurate with the profile of an extended half-life rFVIII product, the pre-defined once-weekly dosing criterion set forth in the research, development, license and supply agreement was not met. To our knowledge, there were no drug-related adverse events, serious adverse events, or rFVIII inhibitors reported to date. Though the trial's pre-defined once-weekly dosing criterion was not met, we intend to explore the potential for future collaborations with Shire.

$7.5 Million Sublicense Payment from Shire plc for certain patents related to our PolyXen technology

In October 2017, we entered into a Right to Sublicense Agreement (the "Sublicense Agreement") with Baxalta Incorporated, Baxalta US Inc., and Baxalta GmbH (collectively, with their affiliates, "Baxalta"), wholly-owned subsidiaries of Shire. Pursuant to the Sublicense Agreement, we granted to Baxalta the right to grant a nonexclusive sublicense to certain patents related to our PolyXen technology that were previously exclusively licensed to Baxalta pursuant to an agreement between us and Baxalta (the "Licensed Patents") in connection with products relating to the treatment of blood and bleeding disorders (the "Covered Products"). The term of the Sublicense Agreement continues on a country-to-country basis until the expiration of the last-to-expire Licensed Patents or upon certification from Baxalta that it is not receiving compensation for sales of Covered Products in a given country, whichever is later (the "Term").

Pursuant to the Sublicense Agreement, Baxalta paid us a one-time payment of seven million five hundred thousand dollars ($7,500,000) in November 2017 and agreed to pay us single digit royalty payments based upon net sales of the Covered Products throughout the Term, each of which is conditioned upon the performance of the sublicense contemplated by the Sublicense Agreement.

Commencement of dosing on XBIO-101 Phase 2 EC Trial

We are currently conducting a Phase 2 trial for XBIO-101, with the first patient dosed in October 2017, and expect to generate preliminary data from this trial before the end of 2018.

- The primary objective of the open-label, multi-center, single-arm, two-period Phase 2 study is to assess the antitumor activity of XBIO-101 in conjunction with progestin therapy as measured by Overall Disease Control Rate in women with recurrent or persistent endometrial carcinoma not amenable to surgical treatment or radiotherapy who have either failed progestin monotherapy or who have been identified as PrR-. Secondary objectives include assessments of efficacy and safety/tolerability parameters.

- The study is expected to enroll a total of 72 women with recurrent or persistent endometrial cancer not amenable to surgical treatment or radiotherapy but suitable to be treated with progestins. All subjects determined to be PrR- at screening, as well as those subjects who experience disease progression after at least 4 weeks of progestin monotherapy, will receive XBIO-101 in combination with continued progestin treatment. Subjects will receive treatment until disease progression as defined according to Response Evaluation Criteria in Solid Tumors ("RECIST") 1.1 criteria.

Our Technology and Drug Candidates

The Technologies

We incorporate our patented and proprietary technologies into a number of drug candidates which are currently under development either in-house or with our biotechnology and pharmaceutical collaborators, with the goal of creating what we believe will be the next-generation of biologic drugs and therapeutics. While we primarily focus on researching and developing oncology drugs, we also have ownership and other economic interests in drugs being developed by our collaborators to treat other conditions. Our patent portfolio spans four core proprietary technologies including two platforms, small molecules and biologics covering multiple drug candidates and indications including XBIO-101, PolyXen, OncoHist and ImuXen.

XBIO-101 — A small molecule therapeutic with the potential to confer sensitivity to hormone therapeutics upon cancer cells that are otherwise insensitive to such treatments. XBIO-101 (sodium cridanimod) belongs to a class of low-molecular weight synthetic interferon inducers. In addition to its immunomodulatory properties, XBIO-101 has been shown to increase levels of progesterone receptor, or PrR, expression in tumor tissue of patients who are PrR-, and thus may restore sensitivity of non-responsive endometrial cancers to hormonal (e.g., progestin) therapy. Based on preclinical observations, XBIO-101 may also be therapeutically relevant in other hormone-resistant cancers, such as triple-negative breast cancer. XBIO-101 has been granted an orphan drug designation by the FDA for the potential treatment of progesterone receptor negative endometrial cancer in conjunction with progesterone therapy.

PolyXen — An enabling biological platform technology designed to extend the circulation time of drug molecules in the human body by chemically attaching polysialic acid, or PSA, to the drug molecule by a process termed polysialylation, thereby creating potentially superior next generation therapeutic candidates. PSA, a biopolymer, comprising a chain of sialic acid molecules, is a natural constituent of the human body, although we obtain our PSA from a bacterial source.

OncoHist — A novel therapeutic platform technology that utilizes the properties of modified human histone H1.3 for targeted cell necrosis or apoptosis (programmed cell death), which may enable OncoHist to treat a broad range of cancer indications. OncoHist, unlike many competing oncology therapies, is based on a molecule occurring naturally in the human body, primarily in the cell nucleus, and is therefore hypothesized to be better tolerated and less immunogenic than other oncology therapies.

ImuXen — A novel liposomal co-entrapment encapsulation technology designed to maximize both cell and immune system mediated responses. The technology is based on the co-entrapment of the nominated antigen(s) in a liposomal vesicle. The technology when applied may create new vaccines and improve the use and efficacy of certain existing human vaccines.

Though we hold a broad patent portfolio, the focus of our internal development efforts is currently limited to research and development of our lead product candidate XBIO-101 because of capital constraints.

In-House Research, Outside Services and Collaborations

Through in-house and partner efforts, we are developing our pipeline of next generation bio-therapeutics and novel oncology drugs based on our XBIO-101 and PolyXen proprietary technologies. In order to do this while efficiently managing our overhead, we rely on in-house research efforts, the services of contract manufacturers and contract research organizations and our strategic collaborations. Accordingly, continuous pipeline growth and advancement of our technologies and drug candidates is dependent, in part, on several important collaborations and strategic arrangements including our arrangements with:

- PJSC Pharmsynthez ("Pharmsynthez"), a Russian pharmaceutical company and presently our majority stockholder; and
- Serum Institute of India Limited ("Serum Institute"), one of the world's largest vaccine manufacturers and one of India's largest biotech companies, as well as a beneficial owner of over 5% of our common stock.

Accordingly, in addition to pursuing the development of our pipeline of next generation bio-therapeutics and novel oncology drugs, we also have significant interests in drug candidates being developed by our collaborators to treat other conditions. We may collect milestone payments and royalties pursuant to these collaborations to the extent that these drugs are successfully developed and marketed. For further detail, please read the section titled "Significant Co-Development Collaborations and Strategic Arrangements" on page 8.

Our Drug Candidate Pipeline

Our product pipeline contains a number of drug candidates under development in-house and drug candidates under development with our biotechnology and pharmaceutical collaborators. The following discussion summarizes key information regarding our current drug candidates, organized by our internal programs and our collaborators' programs:

XBIO-101

XBIO-101 is our most advanced internal candidate with an orphan drug designation from the FDA for the potential treatment of progesterone receptor negative endometrial cancer in conjunction with progesterone therapy. An investigational new drug application, or IND, has been submitted for XBIO-101 and is in effect for our ongoing Phase II clinical trials in the U.S.

Pursuant to the Asset Purchase Agreement, dated as of November 13, 2015 (the "APA"), entered into with Pharmsynthez and AS Kevelt ("Kevelt"), a wholly owned subsidiary of Pharmsynthez, Kevelt and Pharmsynthez transferred to us certain IP rights with respect to XBIO-101, and the worldwide rights to develop, market and license XBIO-101 for certain uses, except for excluded uses within the CIS, in exchange for approximately 3.4 million shares of our common stock. We also acquired Kevelt's orphan drug designation from the FDA for the use of XBIO-101 in the treatment of PrR- endometrial cancer in conjunction with progesterone therapy.

XBIO-101 (sodium cridanimod), belongs to a class of low-molecular weight synthetic interferon, or IFN, inducers and is primarily used in a wide range of therapeutic areas such as antiviral, antibacterial, antitumor, and inflammatory indications due to its ability to modify or regulate one or more immune system functions. We believe XBIO-101 may also prove to be therapeutically relevant in hormone-resistant cancers by increasing the levels of PrR expression in tumor tissue of patients who are PrR deficient. As such, it may restore the sensitivity of non-responsive endometrial cancers to hormonal (e.g., progestin) therapy. Accordingly, we are pursuing the use of XBIO-101 for the treatment of endometrial cancer.

Our decision to investigate XBIO-101 for the treatment of endometrial cancer was based in part on the history of sodium cridanimod in preclinical and clinical research conducted by others, including prior clinical trials conducted and completed in Russia that assessed the efficacy and safety of sodium cridanimod. Sodium cridanimod has been authorized for medicinal use in the Russian Federation for 21 years and over nine million doses have been sold for the treatment of non-cancer indications. XBIO-101 is also known under the brand names Neovir, Camedon and Primavir.

The extensive clinical testing conducted by others, as well as the marketing history of sodium cridanimod, provided support for our authorization to proceed directly with a Phase II efficacy study under our U.S. IND for the use of sodium cridanimod in conjunction with progestin therapy in patients with progestin resistant, recurrent or persistent endometrial cancer. We commenced the Phase II trial under the IND in 2017, with the first patient dosed in October 2017.

ErepoXen

Our second most advanced internal drug candidate is ErepoXen, or polysialylated erythropoietin ("PSA-EPO"). ErepoXen uses our PolyXen platform technology for the treatment of anemia in chronic kidney disease ("CKD") patients. It is designed to reduce the dosing frequency by extending the circulating half-life of the therapeutic in the body. We have terminated our clinical development efforts of ErepoXen and are currently seeking to out-license the drug candidate in our licensed territories.

We have collaboration agreements with SynBio LLC ("SynBio") and Serum Institute to develop and launch ErepoXen in limited markets pursuant to which we will collect royalties if they are successful in these efforts.

Serum Institute conducted Phase I and Phase II clinical trials in 95 human subjects. These safety trials, which had no significant drug-related adverse events, provided us with the data to commence a Phase II, repeat dosing, ICH compliant clinical trial for ErepoXen in Australia, New Zealand and South Africa for CKD patients not on dialysis. We completed three cohorts of this study and then terminated the study. Each cohort represents an increased dose of ErepoXen that is given on a repeat schedule until therapeutic levels of hemoglobin are achieved. In our study there were no serious Treatment Emergent Adverse Events ("TEAE") related to ErepoXen in either cohort 1 or 2. There was one serious TEAE in cohort 3 judged to be possibly related, but not unexpected given the safety profile of other Erythropoietin Stimulating Agents (ESAs).

In addition, Serum Institute finished Phase I/II clinical trials in India of ErepoXen for in-center-dialysis patients. Serum Institute indicated that it will use its data from the Phase I/II clinical trials and data generated from our Phase II trial to further progress clinical trials of ErepoXen in India.

SynBio applied for and received regulatory approval to commence ErepoXen Phase II(b)/III human clinical trials in Russia and is currently recruiting patients. SynBio has indicated that it intends to commence the commercialization and marketing stages of ErepoXen in the Russian and CIS markets subject to approval in such markets.

OncoHist

Our drug candidate OncoHist, which has clinical proof of concept, utilizes the properties of modified human histone H1.3 for targeted cell killing. We were previously researching and developing OncoHist for the treatment of relapsed or resistant acute myeloid leukemia (AML). We anticipate filing an IND application for OncoHist for AML once we are able to raise sufficient capital.

We have a sponsored research agreement with Dana Farber Cancer Institute intended to elucidate OncoHist's mechanism of action as well as to characterize the responsiveness of various AML cell lines to OncoHist. Dr. Richard Stone, MD, Professor of Medicine at Harvard Medical School and Clinical Director of the Adult Leukemia Program at Dana-Farber Cancer Institute, presented data at the 2014 American Society of Hematology meeting (*Blood*, 2014 124(21):3604 OncoHist, an rh Histone 1.3, Is Cytotoxic to Acute Myeloid Leukemia Cells and Results in Altered Downstream Signaling).

We completed non-clinical toxicity studies of OncoHist guided, in part, by clinical data supplied by SynBio and SymbioTec, GmbH, a German company we acquired in 2012 ("SymbioTec"). In August 2015, we had a productive, in-person pre-IND meeting with the FDA where manufacturing and clinical matters were addressed including guidance from the FDA regarding inclusion of an additional indication besides AML in our proposed Phase I clinical trial.

Currently, all our development efforts regarding OncoHist remain on hold.

Pipeline Expansion Opportunities

Operating under licenses from us within their home markets, our collaborators generate pre-clinical and clinical data related to our technologies across a wide spectrum of therapeutic areas. Under these agreements, we retain all rights for major markets and co-own the clinical data. We therefore have the opportunity to utilize the data in our decision-making process regarding development and commercialization in major markets. We expect to be able to utilize the results from substantially all of our clinical toxicity data and other clinical data generated in the development of XBIO-101 and PolyXen, and potentially for OncoHist, and ImuXen, for a variety of orphan oncology indications and next generation biologic drugs.

For example, we believe that we may be able to develop XBIO-101 for other indications. Results from preclinical and exploratory studies conducted by a collaborative partner suggest that XBIO-101 can up-regulate (i.e., increase the levels of) estrogen receptor ("ER") in certain tissue types. Proof of concept studies are being planned to investigate additional therapeutic opportunities for XBIO-101 in hormone-resistant tumor types other than endometrial cancer, including a potential ER clinical biomarker study for triple-negative breast cancer ("TNBC") under our current XBIO-101 IND.

We also believe that the nature of our technologies, including the PolyXen platform, will allow us to pursue additional drug candidates for new indications based on existing and future scientific data.

Significant Co-Development Collaborations and Strategic Arrangements

Shire plc

We are a party to an exclusive research, development and license agreement with Baxalta US Inc. and Baxalta AB, wholly owned subsidiaries of Shire, related to the development of a novel series of polysialylated blood coagulation factors. This collaboration with Shire relies of the Company's PolyXen technology to conjugate PSA to therapeutic blood-clotting factors, with the goal of improving the pharmacokinetic profile and extending the active life of these biologic molecules. The agreement grants Shire a worldwide, exclusive, royalty-bearing license to our PSA patented and proprietary technology in combination with Shire's proprietary molecules designed for the treatment of blood and bleeding disorders. The first program under this agreement was a next generation Factor VIII protein product candidate.

In December 2016, Shire reached a milestone of its Phase 1/2 clinical trial for the treatment of hemophilia with SHP656, triggering a $3.0 million payment to be paid to us pursuant to the agreement with Shire. We determined the milestone to be non-substantive because all significant performance obligations to achieve the contingent payments were the responsibility of Shire with only a negligible amount of our effort to fulfill our obligations, specifically assistance on a research committee. As the amount allocable to the remaining performance period was negligible, we recognized the full $3.0 million in milestone revenue in connection with this collaboration during the year ended December 31, 2016.

In May 2017, we announced that our strategic collaborator, Shire, had terminated further development of SHP656, its polysialylated rFVIII drug candidate being developed using our proprietary PolyXen technology. While Shire's Phase 1/2 trial demonstrated SHP656's efficacy and pharmacokinetic data commensurate with the profile of an extended half-life rFVIII product, the pre-defined once-weekly dosing criterion set forth in the research, development, license and supply agreement was not met. To our knowledge, there were no drug-related adverse events, serious adverse events, or rFVIII inhibitors reported to date. Though the trial's pre-defined once-weekly dosing criterion was not met, we intend to continue to explore the potential for future collaborations with Shire.

In October 2017, we entered into a Sublicense Agreement with Baxalta. Pursuant to the Sublicense Agreement, we granted to Baxalta the right to grant a nonexclusive sublicense to Licensed Patents in connection with the Covered Products. Pursuant to the Sublicense Agreement, Baxalta paid us a one-time payment of seven million five hundred thousand dollars ($7,500,000) in November 2017 and agreed to pay us single digit royalty payments based upon net sales of the Covered Products throughout the Term, each of which is conditioned upon the performance of the sublicense contemplated by the Sublicense Agreement.

SynBio LLC

In August 2011, we entered into a stock subscription and collaborative development agreement with SynBio (the "Co-Development Agreement"), pursuant to which we granted SynBio an exclusive license to develop, market and commercialize certain drug candidates utilizing molecules based on our PolyXen and OncoHist platform technologies in Russia and the CIS, collectively referred to herein as the SynBio Market. In exchange for our granting to SynBio those certain license rights, SynBio granted an exclusive license to us to use any SynBio pre-clinical and clinical data generated by SynBio and to engage in the development and commercialization of drug candidates that may arise from the collaboration in any territory outside of the SynBio Market based upon the Co-Development Agreement.

We hope and expect to mitigate certain technical and commercial risks of drug development by working in collaboration with SynBio. Under the Co-Development Agreement, SynBio is responsible for progressing six new product candidates through human proof of concept trials in Russia as primary validation for the initiation of European Medicines Agency ("EMA") or FDA clinical trials by us.

The primary goal of the Co-Development Agreement is to research and develop drug candidates for planned commercialization using SynBio and our combined respective expertise and technologies. Drug candidates must meet the success criteria as decided upon by a joint steering committee, which includes representation from both SynBio and us, where we have the right to appoint the chair who has the casting vote. Once a potential drug candidate is selected, clinical trials will be separately conducted by each company in their respective territories with the goal to achieve regulatory approval of the products for commercial sale.

SynBio is wholly responsible for funding and conducting their own research and clinical development activities in Russia, and we are wholly responsible for funding and conducting our own research and clinical development activities in the U.S., Europe and elsewhere outside the SynBio Market. There are no milestones or other research-related payments provided for under the Co-Development Agreement other than fees for the provision of each party's respective research supplies based on their technology. For the years ended December 31, 2017 and 2016, we have recognized no supply service revenues in connection with the Co-Development Agreement. Among other provisions, the parties may terminate the Co-Development Agreement in relation to a particular product upon 30 days' written notice, if such party, in its reasonable opinion, believes that a third-party IP right exists, which would have a material effect on the research and/or development of the relevant product. Further, the parties may terminate the Co-Development Agreement if the other party is in material breach of the Co-Development Agreement and, in the case of a breach capable of remedy, the breach is not remedied within 90 days of receiving notice specifying the breach and requiring its remedy, or if the other party becomes insolvent. The parties also may terminate the Co-Development Agreement by immediate written notice to the other party in relation to a specific product such if product does not meet the relevant success criteria for the product.

Concurrent with entering into the Co-Development Agreement, we entered into a stock subscription agreement with SynBio pursuant to which we sold SynBio approximately 1.1 million shares of common stock for proceeds of approximately $18.6 million, making them an affiliate of the Company.

In furtherance of our co-development clinical objectives, on December 31, 2014, we granted SynBio a warrant to purchase 204,394 shares of our common stock that contain vesting triggers based on the achievement by SynBio of certain clinical development objectives within specific timeframes (the "SynBio 2014 Warrant"). Simultaneously with the issuance of the SynBio 2014 Warrant, we granted additional warrants to purchase 9,697 aggregate new shares of our common stock to SynBio and Pharmsynthez non-director designees under the same terms and conditions of the SynBio 2014 Warrant. The SynBio 2014 Warrant expires on December 30, 2019 and no warrants were exercised during the years ended December 31, 2017 and 2016.

On September 23, 2016, SynBio exchanged 970,000 shares of common stock for an equal number of shares of Series A Preferred Stock. SynBio is an affiliate and related party of ours, with a share ownership of approximately 9.4% of the total issued common stock and all 970,000 shares of our outstanding Series A Preferred Stock as of December 31, 2017. The Series A Preferred Stock is convertible at the election of SynBio into shares of our common stock on a one for one basis upon 61 days' prior written notice to us.

PJSC Pharmsynthez

In November 2009, we entered into a collaborative research and development license agreement with Pharmsynthez (the "Pharmsynthez Arrangement") pursuant to which we granted an exclusive license to Pharmsynthez to develop, commercialize and market six product candidates based on our PolyXen and ImuXen technology anywhere within Russia and the CIS, as well as certain clinical and research data developed by us on the six product candidates. In exchange, Pharmsynthez granted us an exclusive license to use any pre-clinical and clinical data developed by Pharmsynthez, within the scope of the Pharmsynthez Arrangement, and to engage in further research, development and commercialization of drug candidates in any territory outside of Russia and the CIS at our own expense.

We expect to mitigate certain risks of drug development by reviewing human clinical data arising out of this collaboration with Pharmsynthez before we take a particular drug candidate into FDA and EMA trials. Under the Pharmsynthez Arrangement, Pharmsynthez is responsible for progressing six new drug candidates through human proof of concept trials in Russia as primary validation prior to the initiation of EMA/FDA clinical trials by us outside of Russia. A joint steering committee, where we have the right to appoint the chair who has the casting vote, was established to facilitate the communication of scientific data and to assist generally with each party's research decisions and to monitor research and development progress under the Pharmsynthez Arrangement.

Pharmsynthez is wholly responsible for funding and conducting its own research and clinical development activities in Russia. We are wholly responsible for funding and conducting our own research and clinical development activities in the U.S., Europe and the rest of the world outside of Russia and the ex-CIS regions. There are no milestones or other research related payments provided for under the Pharmsynthez Agreement other than royalties. Among other provisions, the parties may terminate the agreement in relation to a particular product upon 30 days' written notice, if such party, in its reasonable opinion, believe that a third-party intellectual property right exists which would have a material effect on the research and/or development of the relevant product. Further, the parties may terminate the agreement if the other party is in material breach of the agreement and, in the case of a breach capable of remedy, the breach is not remedied within 90 days of receiving notice specifying the breach and requiring its remedy, or if the other party becomes insolvent. The parties also may terminate the agreement by immediate written notice to the other party in relation to a specific product if such product does not meet the relevant success criteria for the product.

Pharmsynthez is an affiliate of the Company and our majority stockholder. On February 27, 2017, Pharmsynthez acquired 100% of SynBio. As a result, SynBio's ownership stake is reflected as part of Pharmsynthez' share ownership. Pharmsynthez, directly and indirectly through SynBio, has a share ownership in the Company of approximately 61.5% of the total issued common stock as of December 31, 2017.

Serum Institute

In August 2011, we entered into a collaborative research and development agreement (the "Serum Agreement") with Serum Institute amending and restating a series of earlier agreements and providing Serum Institute an exclusive license to use our PolyXen technology to research and develop one potential commercial product, Polysialylated Erythropoietin ("PSA-EPO"). Serum Institute is responsible for conducting all pre-clinical and clinical trials required to achieve regulatory approvals within territories outside of certain predetermined territories assigned to us, which include the U.S., the European Economic Area, and Japan, among other territories, at Serum Institute's own expense. Royalty payments are payable by Serum Institute to us for net sales to certain customers in the Serum Institute sales territory. Royalty payments are payable by us to Serum Institute for net sales received by us over the term of the license. No royalty, revenue or expense was recognized by us related to the Serum Institute arrangement during the years ended December 31, 2017 and 2016. There are no milestone or other research-related payments due under the Serum Agreement.

Through December 31, 2017, we and Serum Institute continued to engage in research and development activities with no resultant commercial products. Among other reasons, the parties may terminate the Serum Agreement by written notice if the other party is in material breach of the Serum Agreement and, in the case of a breach capable of remedy, the breach is not remedied within 90 days of the other party receiving notice specifying the breach and requiring its remedy.

In furtherance of our co-development clinical objectives, on December 31, 2014, we granted to Serum Institute certain warrants to purchase 96,970 shares of our common stock that contain vesting triggers based on the achievement by Serum Institute of certain clinical development objectives within specific timeframes ("Serum 2014 Warrant"). Simultaneously with the issuance of the Serum 2014 Warrant, we issued additional warrants to purchase an aggregate of 4,852 shares of our common stock to Serum Institute non-director designees under the same terms and conditions of the Serum 2014 Warrant. The Serum 2014 Warrant expires on December 30, 2019 and no warrants were exercised during any of the years ended December 31, 2017 and 2016.

In addition, the Serum Agreement allows for Serum Institute to nominate a non-executive director to our Board of Directors as long as Serum Institute or its subsidiaries holds at least 6% of our common stock. Serum Institute is an affiliate and related party of ours, with a share ownership of approximately 7.2% of our total issued common stock as of December 31, 2017.

Our Intellectual Property

We strive to protect and enhance the proprietary technology, inventions, and improvements that are commercially important to our business, including seeking, maintaining and defending patent rights, whether developed internally or licensed from our collaborators or other third-parties. Our policy is to seek to protect our proprietary position by, among other methods, filing patent applications in the United States and in jurisdictions outside of the United States covering our proprietary technology, inventions, improvements and product candidates that are important to the development and implementation of our business. We also rely on trade secrets and know-how relating to our proprietary technology and product candidates, continuing innovation, and in-licensing opportunities to develop, strengthen and maintain our proprietary position in the field of oncology. We also plan to rely on data exclusivity, market exclusivity, and patent term extensions when available. Our commercial success will depend in part on our ability to obtain and maintain patent and other proprietary protection for our technology, inventions, and improvements; to preserve the confidentiality of our trade secrets; to obtain and maintain licenses to use intellectual property owned by third-parties; to defend and enforce our proprietary rights, including any patents that we may own in the future; and to operate without infringing on the valid and enforceable patents and other proprietary rights of third-parties.

Our drug candidates are in various stages of development, each protected by patent and pending patent applications in the U.S. with the United States Patent and Trademark Office ("USPTO") and in certain other developed countries. Our first issued patents are due to begin to expire starting in 2022 with the majority of the existing issued patents expiring between 2025 and 2030.

Our patent strategy is to file patent applications on innovations and improvements in those jurisdictions that comprise the major pharmaceutical markets in the world or locations where a pharmaceutical may be manufactured. These jurisdictions include, but are not limited to the U.S., U.K., Australia, Japan, Canada, South Korea, China, Hong Kong, India, Russia and certain other countries in the European Union (E.U.) and Asia, though we do not necessarily file a patent application in each of these jurisdictions for every patent family.

As of February 16, 2018, we directly or indirectly own, through our wholly-owned subsidiary, Xenetic U.K., and its wholly-owned subsidiaries, Lipoxen, Xenetic Technologies, Inc. and SymbioTec, more than 170 U.S. and international patents and over 40 pending patent applications that cover various aspects of our technologies. We have filed patent applications, and plan to file additional patent applications, covering various aspects of our PolyXen platform technology covering polysialylation and advanced polymer conjugate technologies, as well as our proprietary product candidates, including XBIO-101, ErepoXen and PulmoXen. More specifically, our patents and patent applications cover polymer architecture, drug conjugates, formulations, methods of manufacturing polymers and polymer conjugates and methods of administering polymer conjugates. We will also be filing additional patent applications where possible for XBIO-101 and OncoHist for additional indications.

Our patent portfolio contains patents and patent applications that encompass our OncoHist platform technology including use of histones for the treatment of different cancers. The OncoHist patent portfolio, acquired as part of our acquisition of SymbioTec in January 2012, includes OncoHist, a bis-Met histone. In addition, our licensed patent portfolio includes patents issued in jurisdictions outside of the United States and licensed patent applications pending in jurisdictions outside of the United States that are foreign counterparts to one or more of the foregoing U.S. patents and patent applications. The OncoHist portfolio also includes patents that cover the use of a histone protein as an antibiotic and to threat thrombocytopenia and further as an antimicrobial component of a personal care product.

We have received patent protection for certain therapeutics that use our PolyXen technology linking the specific therapeutic to a PSA. These include, but are not limited to, PSA-erythropoietin ("EPO"), PSA-insulin and PSA-insulin like protein, SHP656 (rFVIII), PSA-DNase I and PSA-granulocyte colony stimulating factor (GCSF). Further patents cover methods to prepare proteins that are linked to a PSA. These method patents include those that link a PSA to a protein in a high pH solution as well as patents that use a process for producing an aldehyde derivative of a sialic acid through the opening and oxidation of a sialic acid unit. For instance, we have patent protection for a PSA linkage that can be at the N-terminus.

We have received patent protection for the production of PSA and the removal of endotoxin during the purification process. The removal of endotoxin occurs through the addition of a high pH solution to the PSA and a process to separate a polydisperse ionically charged polysaccharide, such as PSA, into fractions of different average molecular weight. This is accomplished through the use of a column and elution buffers with different and constant ionic strength and pH, resulting in a fractionated polysaccharide that has a molecular weight polydispersity of 1.1 or lower.

Issued patents can provide protection for varying periods of time, depending upon the date of filing of the patent application, the date of patent issuance, and the legal term of patents in the countries in which they are obtained. In general, patents issued for applications filed in the United States can provide exclusionary rights for 20 years from the earliest effective filing date. In addition, in certain instances, the term of an issued United States patent that covers or claims an FDA approved product can be extended to recapture a portion of the term effectively lost as a result of the FDA regulatory review period, which is called patent term extension. The restoration period cannot be longer than five years and the total patent term, including the restoration period, must not exceed 14 years following FDA approval. The term of patents outside of the United States varies in accordance with the laws of the foreign jurisdiction, but typically is also 20 years from the earliest effective filing date. However, the actual protection afforded by a patent varies on a product-by-product basis, from country-to-country, and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country, and the validity and enforceability of the patent.

In certain situations, where we work with drugs covered by one or more patents, our ability to develop and commercialize our technologies may be affected by limitations in our access to these proprietary drugs. Even if we believe we are free to work with a proprietary drug, we cannot guarantee that we will not be accused of, or be determined to be, infringing a third-party's rights and be prohibited from working with the drug or found liable for damages. Any such restriction on access or liability for damages would have a material adverse effect on our business, results of operations and financial condition.

The patent positions of pharmaceutical and biotechnology companies, such as ours, are uncertain and involve complex legal and factual issues. There can be no assurance that patents that have issued will be held valid and enforceable in a court of law. Even for patents that are held valid and enforceable, the legal process associated with obtaining such a judgment is time consuming and costly. Additionally, issued patents can be subject to opposition or other proceedings that can result in the revocation of the patent or maintenance of the patent in amended form (and potentially in a form that renders the patent without commercially relevant and/or broad coverage). Further, our competitors may be able to circumvent and otherwise design around our patents. Even if a patent is issued and enforceable, because development and commercialization of pharmaceutical products can be subject to substantial delays, patents may expire early and provide only a short period of protection, if any, following the commercialization of a products encompassed by our patent(s). We may have to participate in interference proceedings declared by the USPTO, which could result in a loss of the patent and/or substantial cost to us. Further, we understand that if any of our pending patent applications do not issue, or are deemed invalid following issuance, we may lose valuable IP protection.

U.S. and foreign patent rights and other proprietary rights exist that are owned by third-parties and relate to pharmaceutical compositions and reagents, medical devices and equipment and methods for preparation, packaging and delivery of pharmaceutical compositions. We cannot predict with any certainty which, if any, of these rights will be considered relevant to our technology by authorities in the various jurisdictions where such rights exist, nor can we predict with certainty which, if any, of these rights will or may be asserted against us by third-parties. We could incur substantial costs in defending ourselves and our partners against any such claims. Furthermore, parties making such claims may be able to obtain injunctive or other equitable relief, which could effectively block our ability to develop or commercialize some or all of our products in the U.S. and in other countries and could result in the award of substantial damages. In the event of a claim of infringement, we or our partners may be required to obtain one or more licenses from third-parties. There can be no assurance that we can obtain a license to any technology that we determine we require on reasonable terms, if at all, or that we could develop or otherwise obtain alternative technology. The failure to obtain licenses, if required, may have a material adverse effect on our business, results of operations and financial condition. Further, we may not be able to obtain IP licenses related to the development of our drug candidates on a commercially reasonable basis, if at all.

It is our policy to require our employees and consultants, outside scientific collaborators, sponsored researchers and other advisors who receive confidential information from us to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third-parties except in specific circumstances. The agreements provide that all inventions conceived by an employee shall be our property. There can be no assurance, however, that these agreements will provide meaningful protection or adequate remedies for our trade secrets in the event of unauthorized use or disclosure of such information.

Manufacturing and Supply

We do not have the capability to manufacture our own material necessary to support our drug candidate development programs nor do we intend to acquire such capability as part of our present business strategy. We currently have agreements in place with Serum Institute whereby Serum Institute produces clinical materials for use in the development of drug candidates involving our PolyXen technology. We are currently dependent on Kevelt for clinical materials with respect to our XBIO-101 research program. When and if we decide to restart our OncoHist AML research program, we would be dependent on SynBio for clinical materials with respect to that program. We are investigating second source alternative suppliers for our clinical materials. There can be no assurance that we will be successful in this effort or that if a second source is secured that it would be available to us on commercially reasonable terms or in a timely fashion should any disruption in supply from Serum Institute, Kevelt or SynBio occur.

Government Regulation

General

Government authorities in the United States, at the federal, state and local level, and other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, marketing and export and import of products such as those we are developing. Generally, a new drug must be approved by the FDA through the NDA process and a new biologic must be licensed by the FDA through the BLA process before it may be legally marketed in the United States.

U.S. Regulation

Drug Development Process

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act ("FDCA"), and in the case of biologics, also under the Public Health Service Act, and their implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval may subject an applicant to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, withdrawal of an approval, license revocation, a clinical hold, warning letters or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

The process required by the FDA before a drug or biologic may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests, animal studies and formulation studies in accordance with Good Laboratory Practices ("GLP") regulations and other applicable regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials in accordance with Good Clinical Practice (GCP) regulations to establish the safety and efficacy of the proposed drug for its intended use;
- submission to the FDA of an NDA or BLA;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with current Good Manufacturing Practices ("cGMP") requirements to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity; and
- FDA review and approval of the NDA or BLA.

Once a pharmaceutical candidate is identified for development, it enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information and analytical data, to the FDA as part of the IND. The sponsor will also include a protocol detailing, among other things, the objectives of the first phase of the clinical trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated, if the first phase lends itself to an efficacy evaluation. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Clinical holds also may be imposed by the FDA at any time before or during clinical trials due to safety concerns about ongoing or proposed clinical trials or noncompliance with specific FDA requirements, and the trials may not begin or continue until the FDA notifies the sponsor that the hold has been lifted.

All clinical trials must be conducted under the supervision of one or more qualified investigators in accordance with GCP regulations. They must be conducted under protocols detailing the objectives of the trial, dosing procedures, subject selection and exclusion criteria and the safety and effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND, and timely safety reports must be submitted to the FDA and the investigators for serious and unexpected adverse events. An institutional review board (IRB) at each institution participating in the clinical trial must review and approve each protocol before a clinical trial commences at that institution and must also approve the information regarding the trial and the consent form that must be provided to each trial subject or his or her legal representative, monitor the study until completed and otherwise comply with IRB regulations.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- ***Phase 1***: The drug candidate is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. In the case of some products for severe or life-threatening diseases, such as cancer, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.

- ***Phase 2***: This phase involves clinical trials in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and appropriate dosage.

- ***Phase 3***: Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical study sites. These clinical trials are intended to establish the overall risk-benefit ratio of the drug candidate and provide, if appropriate, an adequate basis for product labeling.

Post-approval trials, sometimes referred to as Phase IV studies, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase IV clinical trials as a condition of approval of an NDA or BLA.

The FDA or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. In addition, some clinical trials are overseen by an independent group of qualified experts organized by the sponsor, known as a data safety monitoring board or committee. Depending on its charter, this group may determine whether a trial may move forward at designated check points based on access to certain data from the trial.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final drug. In addition, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life.

While the IND is active and before approval, progress reports summarizing the results of the clinical trials and nonclinical studies performed since the last progress report must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and investigators for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the same or similar drugs, findings from animal or in-vitro testing suggesting a significant risk to humans, and any clinically important increased incidence of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure.

There are also requirements governing the reporting of ongoing clinical trials and completed trial results to public registries. Sponsors of certain clinical trials of FDA-regulated products are required to register and disclose specified clinical trial information, which is publicly available at www.clinicaltrials.gov. Information related to the product, patient population, phase of investigation, trial sites and investigators and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed until the new product or new indication being studied has been approved.

United States Market Approval Process

The results of product development, preclinical and other non-clinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling and other relevant information are submitted to the FDA as part of an NDA or BLA requesting approval to market the product. The submission of an NDA or BLA is subject to the payment of user fees; a waiver of such fees may be obtained under certain limited circumstances. The FDA reviews all NDAs and BLAs submitted to ensure that they are sufficiently complete for substantive review before it accepts them for filing. The FDA may request additional information rather than accept an NDA or BLA for filing. In this event, the NDA or BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing.

Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA may refer the NDA or BLA to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. The approval process is lengthy and often difficult, and the FDA may refuse to approve an NDA or BLA if the applicable regulatory criteria are not satisfied or may require additional clinical or other data and information. Even if such data and information are submitted, the FDA may ultimately decide that the NDA or BLA does not satisfy the criteria for approval. The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP-compliant to assure and preserve the product's identity, strength, quality and purity. The FDA reviews a BLA to determine, among other things whether the product is safe, pure and potent and the facility in which it is manufactured, processed, packed or held meets standards designed to assure the product's continued safety, purity and potency. Before approving an NDA or BLA, the FDA will inspect the facility or facilities where the product is manufactured.

After the FDA evaluates an NDA or BLA, it will issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application will not be approved in its present form. A Complete Response Letter usually describes the specific deficiencies in the NDA or BLA identified by the FDA and may require additional clinical data, such as an additional pivotal Phase 3 trial or other significant and time-consuming requirements related to clinical trials, nonclinical studies or manufacturing. If a Complete Response Letter is issued, the sponsor must resubmit the NDA or BLA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may decide that the NDA or BLA does not satisfy the criteria for approval.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. In addition, the FDA may require a sponsor to conduct Phase 4 testing, which involves clinical trials designed to further assess a drug's safety and effectiveness after NDA or BLA approval, and may require testing and surveillance programs to monitor the safety of approved products which have been commercialized. The FDA may also place other conditions on approval including the requirement for a risk evaluation and mitigation strategy (REMS) to assure the safe use of the drug. If the FDA concludes a REMS is needed, the sponsor of the NDA or BLA must submit a proposed REMS. The FDA will not approve the NDA or BLA without an approved REMS, if required. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Marketing approval may be withdrawn for noncompliance with regulatory requirements or if problems occur following initial marketing.

Orphan Drug Act

The Orphan Drug Act provides incentives to manufacturers to develop and market drugs or biologics for rare diseases and conditions affecting fewer than 200,000 persons in the U.S. at the time of application for Orphan Drug Designation, or for a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug or biologic will be recovered from sales in the United States. The first developer to receive FDA marketing approval for an orphan drug is entitled to a seven-year exclusive marketing period in the U.S. for that product. However, a drug that the FDA considers to be clinically superior to, or different from, another approved orphan drug, even though for the same indication, may also obtain approval in the U.S. during the seven-year exclusive marketing period. In addition, holders of exclusivity for orphan drugs are expected to assure the availability of sufficient quantities of their orphan drugs to meet the needs of patients. Failure to do so could result in the withdrawal of marketing exclusivity for the drug.

Pediatric Information

Under the Pediatric Research Equity Act of 2007 ("PREA"), NDAs or BLAs or supplements to NDAs or BLAs must contain data to assess the safety and effectiveness of the drug for the claimed indication(s) in all relevant pediatric sub-populations and to support dosing and administration for each pediatric sub-population for which the drug is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers. Unless otherwise required by regulation, PREA does not apply to any drug for an indication for which orphan drug designation has been granted. The Best Pharmaceuticals for Children Act ("BPCA") provides sponsors of NDAs with an additional six-month period of market exclusivity for all unexpired patent or non-patent exclusivity on all forms of the drug containing the active moiety if the sponsor submits results of pediatric studies specifically requested by the FDA under BPCA within required timeframes. The Biologics Price Competition and Innovation Act provides sponsors of BLAs an additional six-month extension for all unexpired non-patent market exclusivity on all forms of the biologic containing the active moiety pursuant to the BPCA if the conditions under the BPCA are met.

The Food and Drug Administration Safety and Innovation Act ("FDASIA"), which was signed into law on July 9, 2012, amended the FDCA. FDASIA requires that a sponsor who is planning to submit a marketing application for a drug or biological product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial Pediatric Study Plan ("PSP") within sixty days of an end-of-Phase II meeting or as may be agreed between the sponsor and FDA. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. FDA and the sponsor must reach agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from nonclinical studies, early phase clinical trials, and/or other clinical development programs.

Expedited Development and Review Programs

The FDA has a Fast Track program that is intended to expedite or facilitate the process for reviewing new drugs and biological products that meet certain criteria. Specifically, new drugs and biological products are eligible for Fast Track designation if they are intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a new drug or biologic may request the FDA to designate the drug or biologic as a Fast Track product at any time during the clinical development of the product. Unique to a Fast Track product, the FDA may consider for review sections of the marketing application on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the application, the FDA agrees to accept sections of the application and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application.

Any product submitted to the FDA for marketing, including under a Fast Track program, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. Fast Track designation, priority review and accelerated approval do not change the standards for approval but may expedite the development or approval process. Any product is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis or prevention of a disease compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug or biological product designated for priority review in an effort to facilitate the review. Additionally, a product may be eligible for accelerated approval. Drug or biological products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval, which means that they may be approved on the basis of adequate and well-controlled clinical trials establishing that the product has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity. As a condition of approval, the FDA may require that a sponsor of a drug or biological product receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. If the FDA concludes that a drug shown to be effective can be safely used only if distribution or use is restricted, it will require such post-marketing restrictions as it deems necessary to assure safe use of the drug, such as distribution restricted to certain facilities or physicians with special training or experience; or distribution conditioned on the performance of specified medical procedures.

FDASIA established a new category of drugs and biologics referred to as "breakthrough therapies" that may be eligible to receive Breakthrough Therapy Designation. A sponsor may seek FDA designation of a drug or biologic candidate as a "breakthrough therapy" if the product is intended, alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the Fast Track program features, as well as more intensive FDA interaction and guidance. The Breakthrough Therapy Designation is a distinct status from both accelerated approval and priority review, which can also be granted to the same drug if relevant criteria are met. If a product is designated as breakthrough therapy, the FDA will expedite the development and review of such drug. All requests for breakthrough therapy designation will be reviewed within 60 days of receipt, and the FDA will either grant or deny the request.

Post-Approval Requirements

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements or standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. After approval, some types of changes to the approved product, such as adding new indications, certain manufacturing changes and additional labeling claims, are subject to further FDA review and approval. Drug and biologics manufacturers and other entities involved in the manufacture and distribution of approved drugs and biologics are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP regulations and other laws and regulations.

U.S. Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of the FDA approval of our drug candidates, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA or BLA plus the time between the submission date of an NDA or BLA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we intend to apply for restoration of patent term for one of our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant NDA or BLA.

Marketing exclusivity provisions under the FDCA can also delay the submission or the approval of certain marketing applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to obtain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application (ANDA), or a 505(b)(2) NDA submitted by another company for another drug based on the same active moiety, regardless of whether the drug is intended for the same indication as the original innovator drug or for another indication, where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder. The FDCA also provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the active agent for the original indication or condition of use. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the pre-clinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Pediatric exclusivity is another type of regulatory market exclusivity in the United States under the BPCA. Pediatric exclusivity provides for an additional six months of marketing exclusivity if a sponsor conducts clinical trials in children as addressed in the section named "Pediatric Information" above. In addition, orphan drug exclusivity, as described above, may offer a seven-year period of marketing exclusivity, except in certain circumstances.

Foreign Regulation

In addition to regulations in the United States, we will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our drug candidates.

Whether or not we obtain FDA approval for our drug candidates, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the drug candidates in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application much like the IND prior to the commencement of human clinical trials. In the European Union, for example, a CTA must be submitted to each country's national health authority and an independent ethics committee, much like the FDA and the IRB, respectively. Once the CTA is approved in accordance with a country's requirements, clinical study development may proceed.

The requirements and process governing the conduct of clinical trials, product approval and licensing, pricing and reimbursement vary from country to country. In all cases, the clinical trials are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

To obtain regulatory approval of an investigational drug or biological product under European Union regulatory systems, we must submit a marketing authorization application. The application used to file the NDA or BLA in the United States is similar to that required in the European Union, with the exception of, among other things, country-specific document requirements. The European Union also provides opportunities for market exclusivity. For example, in the European Union, upon receiving marketing authorization, new chemical entities generally receive eight years of data exclusivity and an additional two years of market exclusivity. If granted, data exclusivity prevents regulatory authorities in the European Union from referencing the innovator's data to assess a generic application. During the additional two-year period of market exclusivity, a generic marketing authorization can be submitted, and the innovator's data may be referenced, but no generic product can be marketed until the expiration of the market exclusivity. However, there is no guarantee that a product will be considered by the European Union's regulatory authorities to be a new chemical entity, and products may not qualify for data exclusivity. Products receiving orphan designation in the European Union can receive ten years of market exclusivity, during which time no similar medicinal product for the same indication may be placed on the market. An orphan product can also obtain an additional two years of market exclusivity in the European Union for pediatric studies. No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications.

The criteria for designating an "orphan medicinal product" in the European Union are similar in principle to those in the United States. Under Article 3 of Regulation (EC) 141/2000, a medicinal product may be designated as orphan if (1) it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (2) either (a) such condition affects no more than five in 10,000 persons in the European Union when the application is made, or (b) the product, without the benefits derived from orphan status, would not generate sufficient return in the European Union to justify investment; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the European Union, or if such a method exists, the product will be of significant benefit to those affected by the condition, as defined in Regulation (EC) 847/2000. Orphan medicinal products are eligible for financial incentives such as reduction of fees or fee waivers and are, upon grant of a marketing authorization, entitled to ten years of market exclusivity for the approved therapeutic indication. The application for orphan drug designation must be submitted before the application for marketing authorization. The applicant will receive a fee reduction for the marketing authorization application if the orphan drug designation has been granted, but not if the designation is still pending at the time the marketing authorization is submitted. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The 10-year market exclusivity may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation, for example, if the product is sufficiently profitable not to justify maintenance of market exclusivity. In addition, marketing authorization may be granted to a similar product for the same indication at any time if:

- the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior;
- the applicant consents to a second orphan medicinal product application; or
- the applicant cannot supply enough orphan medicinal product.

For other countries outside of the European Union, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical studies, product licensing or approval, pricing and reimbursement vary from country to country. In all cases, again, the clinical studies are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Other Regulatory Matters

Manufacturing, sales, promotion and other activities following product approval are also potentially subject to regulation by numerous regulatory authorities in addition to the FDA, including, in the United States, the Centers for Medicare & Medicaid Services, other divisions of the Department of Health and Human Services, the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency and state and local governments. In the United States, sales, marketing and scientific/educational programs must also comply with state and federal fraud and abuse laws, including state and federal anti-kickback, false claims, data privacy and security and physician payment transparency laws. Pricing and rebate programs must comply with the Medicaid rebate requirements of the U.S. Omnibus Budget Reconciliation Act of 1990 and more recent requirements in the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, collectively the Affordable Care Act. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. The handling of any controlled substances must comply with the U.S. Controlled Substances Act and Controlled Substances Import and Export Act. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, sales, promotion and other activities are also potentially subject to federal and state consumer protection and unfair competition laws.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

The failure to comply with regulatory requirements may subject us to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in criminal prosecution, fines or other penalties, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of product approvals, or refusal to allow a firm to enter into supply contracts, including government contracts. In addition, even if a firm complies with FDA and other requirements, new information regarding the safety or efficacy of a product could lead the FDA to modify or withdraw product approval. Prohibitions or restrictions on sales or withdrawal of future products marketed by us could materially affect our business in an adverse way.

Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

Environmental Regulation

In addition to being subject to extensive regulation by the FDA, we must also comply with environmental regulation insofar as such regulation applies to us or our drug candidates. Our costs of compliance with environmental regulation as applied to similar pharmaceutical companies are minimal, since we do not currently, nor do we intend to, engage in the manufacturing of any of our drug candidates. We currently use unaffiliated manufacturers to produce all of our drug candidate material and receive final material from such manufacturer, without any involvement on our part in the manufacturing process at any stage of the process.

Although we believe that our safety procedures for using, handling, storing and disposing of our drug candidate materials comply with the environmental standards required by state and federal laws and regulations, we cannot completely eliminate the risk of accidental contamination or injury from these materials. We do not carry a specific insurance policy to mitigate this risk to us or to the environment.

Research and Development Expenses

Research and development activities include personnel costs, research supplies, clinical and pre-clinical study costs. Such expenses related to the research and development of our drug candidates totaled $4.1 million for the year ended December 31, 2017 and $43.7 million for the year ended December 31, 2016.

Employees

At December 31, 2017, we employed five full-time employees. We are not a party to any collective bargaining agreement with our employees; nor are any of our employees a member of any labor unions. We are subject to certain statutory and contractual obligations in instances where we terminate U.K.-based employees. These obligations, which are ordinary and customary in the U.K., generally range from one to 12 months of wages for terminated employees and would not be expected to represent a material adverse effect to us.

To complement our own professional staff, we utilize specialists in regulatory affairs, pharmacovigilance, process engineering, manufacturing, quality assurance, clinical development and business development. These individuals include scientific advisors as well as independent consultants.

Competition

The pharmaceutical and biotechnology industries are characterized by intense competition and rely heavily on the ability to move quickly, adapt to changing medical and market needs, and to develop and maintain strong intellectual property positions. We believe that the development experience of our scientific and management team, as well as the strength and promise of our drug candidates, provide us with a competitive advantage; nevertheless, we face potential competition from a myriad of sources many of which operate with greater resources and more mature products. These include pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions. Competition is intense and expected to increase.

Product and Technology Specific Competition

XBIO-101 for Endometrial Cancer (EC) and Triple Negative Breast Cancer (TNBC)

Current standard of care treatments for EC and TNBC include radiation, surgery as well as certain chemotherapeutic and antineoplastic agents, particularly platinum-based agents, including but not limited to Taxol, Taxane, anthracycline, carboplatin, doxorubicin, cisplatin, ifosfamide, and topotecan.

A number of additional therapeutic classes are in development worldwide, including but not limited to antibodies, antibody-drug conjugates (ADCs), and immunotherapies (e.g., bevacizumab and GALE-301/GALE-302, respectively). Additionally, there are a number of targeted agents including inhibitors that target the PI3K/Akt/mTOR pathway (such as AKT inhibitor ARQ-092) and other kinase inhibitors. The aforementioned therapeutics and therapeutic classes may be used either alone or in combination. Companies engaged in clinical development of these products for endometrial cancer include but are not limited to:

- Antibodies/Immunotherapies: Galena BioPharma Inc.; Merck Sharp & Dohme Corp.; Immunogen, Inc.; Immunomedics, Inc.; Genentech, Inc.; Macrogenics, Inc.; Genmab A/S; Incyte Corporation; Eisai Inc.; and Bayer AG.
- Targeted Agents: ArQule, Inc.; AstraZeneca plc; Novartis International AG; Daiichi Sankyo Inc.; GlaxoSmithKline plc; and Advenchen Laboratories, LLC.

PSA for Drug Delivery

Current delivery platforms include PEG, FC-fusion, albumin infusion, HES, depot, CTP-fusion.

Market participants include Nektar's PEG technology, Flamel's Medusa platform offering, a hydrogel depot formulation, Versartis' XTEN technology which utilizes recombinant polypeptide fusion protein, nanoparticle technology from Alkermes, Durect Corp's long-acting technology, Debiopharm Group's drug delivery based on polylactic-co-glycolic acid (PLGA), and Halozyme's ENHANZE drug delivery technology platform.

We also expect to compete with academic institutions and other smaller pharmaceutical companies during the drug development stage of our progress. In addition to competing with universities and other research institutions in the development of drug products, therapies, technologies and processes, we may compete with other companies in acquiring rights to products or technologies from universities. There can be no assurance that our products or drug candidates will be more effective or achieve greater market acceptance than competitive products, or that these companies will not succeed in developing products and technologies that are more effective than those being developed for us or that would render our products and technologies less competitive or obsolete.

Available Information

Our website address is www.xeneticbio.com. The information in, or that can be accessed through, our website is not part of this Annual Report on Form 10-K. Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K and amendments to those reports are available, free of charge, on or through our website as soon as practicable after we electronically file such forms, or furnish them to, the SEC. The public may read and copy any materials we file with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Washington, D.C. 20549. Information on the operations of the Public Reference Room can be obtained by calling 1-800-SEC-0330. The SEC maintains an internet site that contains reports, proxy and information statements and other information regarding our filings at www.sec.gov.

In addition to disclosing current information pursuant to Section 13 or 15(d) of the Exchange Act and for reports of information required to be disclosed by Regulation FD through our SEC filings, we also intend to disclose such current information through our investor relations website, press releases, public conference calls and webcasts.

ITEM 1A – RISK FACTORS

Our business is subject to numerous risks. You should consider carefully the risks and uncertainties described below, in addition to other information contained in this Annual Report as well as our other public filings with the Securities and Exchange Commission. Any of the following risks could have a material adverse effect on our business, financial condition, results of operations and prospects and cause the trading price of our common stock to decline.

Risks Related to Our Financial Condition and Capital Requirements

We have never been profitable and may never achieve or sustain profitability.

We are a clinical stage biopharmaceutical company with a limited operating history. Pharmaceutical product and technology development is a highly speculative undertaking and involves a substantial degree of risk. To date, we have focused primarily on developing our lead drug candidates, XBIO-101 and PolyXen, our biological platform technology, and researching additional drug candidates. We have no products approved for commercial sale and have generated only limited revenue to date. Due to capital constraints, we are currently focused solely on the development of XBIO-101. We continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we have never been profitable and we may not achieve profitability in the foreseeable future, if at all. Our ability to generate profits in the future will depend on a number of factors, including:

- Funding the costs relating to the research and development, regulatory approval, commercialization and sale and marketing of our drug candidates and technologies, in particular, XBIO-101;
- Market acceptance of our drug candidates and technologies, in particular, XBIO-101;
- Costs of acquiring and developing new drug candidates and technologies;
- Ability to bring our drug candidates to market, in particular, XBIO-101;
- General and administrative costs relating to our operations;
- Increases in our research and development costs;
- Charges related to purchases of technology or other assets;
- Establishing, maintaining and protecting our intellectual property rights;
- Attracting, hiring and retaining qualified personnel; and
- Our ability to raise additional capital.

As of December 31, 2017, we had an accumulated deficit of approximately $145.9 million. Substantial doubt exists about our ability to continue as a going concern as a result of anticipated capital needs. We expect to incur additional significant operating losses as we expand our research and development activities and our commercialization, marketing and sales efforts. We may also encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. In addition, because of the numerous risks and uncertainties associated with pharmaceutical product development, including that our current drug candidates may not achieve the clinical endpoints of applicable trials, we are unable to predict the timing or amount of increased expenses, and if or when we will achieve or maintain profitability. If we are unable to generate sufficient revenue from our operations to pay expenses or we are unable to obtain additional financing on commercially reasonable terms, our business, financial condition and results of operations may be materially and adversely affected.

Our independent registered public accounting firm and the Company have expressed substantial doubt about our ability to continue as a going concern.

We have concluded there is substantial doubt about our ability to continue as a going concern. As described in their audit report, our auditors have included an explanatory paragraph that states that we have incurred recurring losses and negative cash flows from operations since inception and have an accumulated deficit at December 31, 2017 of $145.9 million. These matters raise substantial doubt about our ability to continue as a going concern. Our consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. If we cannot continue as a viable entity, our stockholders may lose some or all of their investment in us.

We will require substantial additional funding to achieve our goals. Failure to obtain this necessary capital when needed on acceptable terms, or at all, may force us to delay, limit or terminate our product development efforts, other operations or commercialization efforts.

We are currently advancing XBIO-101 through clinical development. Developing drug candidates is an expensive, risky and lengthy process, and we expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development of, continue and initiate clinical trials of, and seek marketing approval for, our drug candidates.

As of December 31, 2017, we had cash and cash equivalents of $5.5 million. We expect that we will require additional capital to complete clinical trials, obtain regulatory approval for, and to commercialize, our drug candidates, including our other preclinical drug candidates and our future drug candidates. However, our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings, third-party funding, marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or a combination of these approaches. In any event, we will require additional capital to pursue preclinical and clinical activities, pursue regulatory approval for, and to commercialize, our longer term pipeline drug candidates. Even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic considerations.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our drug candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. Moreover, the terms of any financing may negatively impact the holdings or the rights of our stockholders, and the issuance of additional securities, whether equity or debt, by us or the possibility of such issuance may cause the market price of our shares to decline. The incurrence of indebtedness could result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants, such as 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. Even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or for specific strategic considerations.

If we are unable to obtain funding on a timely basis, we may be required to significantly curtail, delay or discontinue our clinical development program or the commercialization of any drug candidates. We may also be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could harm our business, financial condition and results of operations.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or drug candidates.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity and debt financings, as well as selectively continuing to enter into collaborations, strategic alliances and licensing arrangements. We do not currently have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, equity interests will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, and may be secured by all or a portion of our assets.

If we raise funds by selectively continuing to enter into collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish additional valuable rights to our technologies, future revenue streams, research programs or drug candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market drug candidates that we would otherwise prefer to develop and market ourselves. If we are unable to raise additional funds through collaborations, strategic alliances or licensing arrangements, we may be required to terminate product development or future commercialization efforts or to cease operations altogether.

We plan to use potential future operating losses and our federal and state net operating loss, or NOL, carryforwards to offset taxable income from revenue generated from operations or corporate collaborations. However, our ability to use NOL carryforwards could be limited as a result of issuance of equity securities.

We plan to use our current year operating losses to offset taxable income from any future revenue generated from operations or corporate collaborations. To the extent that our taxable income exceeds any current year operating losses, we plan to use our NOL carryforwards to offset income that would otherwise be taxable. However, under the Tax Reform Act of 1986, the amount of benefits from our NOL carryforwards may be impaired or limited if we incur a cumulative ownership change of more than 50%, as interpreted by the U.S. Internal Revenue Service, over a three-year period. As a result, our use of federal NOL carryforwards could be limited by the provisions of Section 382 of the U.S. Internal Revenue Code of 1986, as amended (the "Code"), depending upon the timing and amount of additional equity securities that we issue. In addition, we have not performed an analysis of limitations, and we may have experienced an ownership change under Section 382 as a result of past financings. State NOL carryforwards may be similarly limited. Any such disallowances may result in greater tax liabilities than we would incur in the absence of such a limitation and any increased liabilities could adversely affect our business, results of operations, financial condition and cash flow.

Risks Related to the Discovery and Development of our Pharmaceutical Products

We are an early stage company in the business of developing pharmaceutical products including drug candidates and technologies. Given the uncertainty of such development, our business operations may never fully materialize and create value for investors.

We currently do not have any products that have gained marketing approval. We have invested substantially all of our efforts and financial resources developing ErepoXen, OncoHist and XBIO-101. XBIO-101, our lead and currently only active candidate, is in Phase II clinical development. Our revenues to date consist primarily of collaboration revenue from a single partner and not from product sales or royalties. Our ability to generate product revenues, which may not occur for several years, if ever, will depend on the successful development and eventual commercialization of our drug candidates. We currently generate no revenues from sales of any drugs, and we may never be able to develop or commercialize a marketable drug. Each of our drug candidates will require development, management of development and manufacturing activities, marketing approval in multiple jurisdictions, obtaining manufacturing supply, building of a commercial organization, substantial investment and significant marketing efforts before we generate any revenues from drug sales. We have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the pharmaceutical area. For example, to execute our business plan, we will need to successfully:

- Execute development activities for our drug candidates, including successful enrollment in and completion of clinical trials;
- Obtain required marketing approvals for the development and commercialization of our drug candidates;
- Obtain and maintain patent and trade secret protection or regulatory exclusivity for our drug candidates;
- Protect, leverage and expand our intellectual property portfolio;
- Establish and maintain clinical and commercial manufacturing capabilities or make arrangements with third-party manufacturers for clinical and commercial manufacturing;
- Build and maintain robust sales, distribution and marketing capabilities, either on our own or in collaboration with strategic partners, if our drug candidates are approved;
- Gain acceptance for our drug candidates, if approved, by patients, the medical community and third party payors;
- Effectively compete with other therapies;
- Obtain and maintain healthcare coverages and adequate reimbursement;
- Maintain a continued acceptable safety profile for our drug candidates following approval;
- Develop and maintain any strategic relationships we elect to enter into, if any;
- Enforce and defend intellectual property rights and claims; and
- Manage our spending as costs and expenses increase due to preclinical development, clinical trials, marketing approvals and commercialization.

We may find it difficult to enroll patients in our clinical studies, which could delay or prevent clinical studies of our pharmaceutical products.

Identifying and qualifying patients to participate in clinical studies of our pharmaceutical products is critical to our success. The timing of our clinical studies depends on the speed at which we can recruit patients to participate in testing our pharmaceutical products. We may experience delays. If patients are unwilling to participate in our clinical studies because of negative publicity from adverse events in the biopharmaceutical industries or for other reasons, including competitive clinical studies for similar patient populations, the timeline for recruiting patients, conducting studies and obtaining regulatory approval of potential products may be delayed. These delays could result in increased costs, delays in advancing our product development, delays in testing the effectiveness of our technology or termination of the clinical studies altogether.

We may not be able to identify, recruit and enroll a sufficient number of patients, or those with required or desired characteristics to achieve diversity in a study, to complete our clinical studies in a timely manner. Patient enrollment is affected by factors including:

- Severity of the disease under investigation;
- Real or perceived availability of alternative treatments;
- Size and nature of the patient population;
- Eligibility criteria for and design of the trial in question;
- Perceived risks and benefits of the drug candidate under study;
- Proximity and availability of clinical sites for prospective patients;
- Ongoing clinical trials of potentially competitive agents;
- Physicians' and patients' perceptions as to the potential advantages of our drug candidates being studied in relation to available therapies or other products under development;
- Our Contract Research Organization's (CRO) and our trial sites' efforts to facilitate timely enrollment in clinical trials;
- Patient referral practices of physicians; and
- The need to monitor patients and collect patient data adequately during and after treatment.

We may not be able to initiate or continue clinical studies if we cannot enroll a sufficient number of eligible patients to participate in the clinical studies required by the FDA or other regulatory agencies. Our ability to successfully initiate, enroll and complete a clinical study in any foreign country is subject to numerous risks unique to conducting business in foreign countries, including:

- Difficulty in establishing or managing relationships with contract research organizations and physicians;
- Different standards for the conduct of clinical studies;
- Our inability to locate qualified local consultants, physicians and partners; and
- The potential burden of complying with a variety of foreign laws, medical standards and regulatory requirements, including the regulation of pharmaceutical and biotechnology products and treatment.

If we have difficulty enrolling a sufficient number of patients to conduct our clinical studies as planned, we may need to delay, limit or terminate ongoing or planned clinical studies, any of which would have an adverse effect on our business.

We may encounter substantial delays in commencement, enrollment or completion of our clinical trials or we may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities, which could prevent us from commercializing our current and future drug candidates on a timely basis, if at all.

Before obtaining marketing approval from regulatory authorities for the sale of our current and future drug candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the drug candidates. We cannot guarantee that any clinical studies will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical studies can occur at any stage of testing. Events that may prevent successful or timely completion of clinical development include:

- Delays in reaching a consensus with regulatory agencies on study design;
- Delays in reaching agreement on acceptable terms with prospective CROs and clinical study sites;
- Delays in obtaining required Institutional Review Board, or Independent Ethics Committee approval at each clinical study site;
- Delays in recruiting suitable patients to participate in our clinical studies;
- Imposition of a clinical hold by regulatory agencies, including after an inspection of our clinical study operations or study sites;
- Failure by our CROs, other third-parties or us to adhere to clinical study requirements;
- Failure to perform in accordance with the FDA's good clinical practices (GCP), or applicable regulatory requirements in other countries;
- Delays in the testing, validation, manufacturing and delivery of our drug candidates to the clinical sites;
- Delays in having patients complete participation in a study or return for post-treatment follow-up;
- Clinical study sites or patients dropping out of a study;
- Occurrence of serious adverse events associated with the drug candidate that are viewed to outweigh its potential benefits; or
- Changes in regulatory requirements and guidance that require amending or submitting new clinical protocols.

Any inability to successfully complete preclinical studies and clinical trials could result in additional costs to us or impair our ability to generate revenues from product sales, regulatory and commercialization milestones and royalties. In addition, if we make manufacturing or formulation changes to our drug candidates, we may need to conduct additional studies to bridge our modified drug candidates to earlier versions. Clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our drug candidates or allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our drug candidates and may harm our business, financial condition, results of operations and prospects.

If the results of our clinical studies are inconclusive or if there are safety concerns or adverse events associated with our pharmaceutical products, we may:

- Be delayed in obtaining marketing approval or licenses for our drug candidates, if at all;
- Obtain approval for indications or patient populations that are not as broad as intended or desired;
- Obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- Be subject to changes with the way the product is administered;
- Be required to perform additional clinical studies to support approval or be subject to additional post-marketing testing requirements;
- Have regulatory authorities withdraw their approval of the product or impose restrictions on its distribution in the form of a modified risk evaluation and mitigation strategy;
- Be subject to the addition of labeling statements, such as warnings or contraindications;
- Be sued; or
- Experience damage to our reputation.

As described above, any of these events could prevent us from achieving or maintaining market acceptance of our pharmaceutical products and impair our ability to generate revenues.

Clinical trials may fail to demonstrate the safety and efficacy of our pharmaceutical drug candidates and could prevent or significantly delay regulatory approval.

Before receiving NDA or BLA approval to commercialize a drug candidate, we must demonstrate to the FDA, with substantial evidence from well controlled clinical trials, that the drug candidate is both safe and effective or the biologics is safe, pure and potent. If these trials or future clinical trials are unsuccessful, our business and reputation would be harmed and our stock price would most likely be adversely affected.

Clinical failure can occur at any stage of clinical development. Clinical trials may produce negative or inconclusive results, and we or any of our current and future collaborators may decide, or regulators may require us, to conduct additional clinical or preclinical testing. We will be required to demonstrate with substantial evidence through well-controlled clinical trials that our drug candidates are as safe and effective for use in a specific patient population as the respective reference products before we can seek regulatory approvals for their commercial sale. Success in early clinical trials does not mean that future larger registration clinical trials will be successful because drug candidates in later-stage clinical trials may fail to demonstrate equivalent safety and efficacy to the satisfaction of the FDA and foreign regulatory agencies despite having progressed through initial clinical trials. Drug candidates that have shown promising results in early clinical trials may still fail in subsequent confirmatory clinical trials. Similarly, the outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. A number of companies in the pharmaceutical industry, including those with greater resources and experience than us, have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in earlier clinical trials.

In addition, the design of a clinical trial can determine whether its results will support approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. We may be unable to design and execute a clinical trial to support regulatory approval. In some instances, there can be significant variability in safety or efficacy results between different trials of the same drug candidate due to numerous factors, including but not limited to changes in trial protocols, differences in size and type of the patient populations, adherence to the dosing regimen and the rate of dropout among clinical trial participants.

Because of these risks, our research and development efforts, and those of our collaborative partners, may not result in any commercially viable products. If a significant portion of these development efforts is not successfully completed, or if required regulatory approvals are not obtained by us or our partners, or any approved products are not commercially successful, we are not likely to generate significant revenues or become profitable.

Our business is substantially dependent on the success of clinical trials for XBIO-101 and our ability to achieve regulatory approval for the marketing of this product.

We currently have no products on the market, and our lead product candidate, XBIO-101, is currently in early clinical development. There are no other product candidates in development at this time due to capital constraints. Our business depends almost entirely on the successful clinical development, regulatory approval and commercialization of XBIO-101 and it will require substantial additional clinical development and regulatory approval efforts before we are permitted to commence its commercialization, if ever. The clinical trials and manufacturing and marketing of XBIO-101 and any other product candidates will be subject to extensive and rigorous review and regulation by numerous government authorities in the United States, the European Union and other jurisdictions where we intend to test and, if approved, market our product candidates. Before obtaining regulatory approvals for the commercial sale of any product candidate, we must demonstrate through preclinical testing and clinical trials that the product candidate is safe and effective for use in each target indication, and potentially in specific patient populations. This process can take many years and may include post-marketing studies and surveillance, which would require the expenditure of substantial resources beyond the proceeds we have currently raised. Of the large number of drugs in development for approval in the United States and the European Union, only a small percentage successfully complete the FDA or European Medicines Agency, or EMA, regulatory approval processes, as applicable, and are commercialized. Accordingly, even if we are able to obtain the requisite financing to continue to fund our research, development and clinical programs, we cannot assure you that XBIO-101 or any of our other product candidates will be successfully developed or commercialized.

We initiated our Phase 2 clinical trial for XBIO-101 in PrR- EC patients in the first half of 2017 with first patient dosing in October 2017. There are no assurances that the Phase 2 clinical trial for XBIO-101 will be timely completed, if at all, and if completed, there can be no assurances that the results will be successful.

Even if we complete the necessary preclinical and clinical studies, we cannot predict when or if we will obtain regulatory approval to commercialize a drug candidate or the approval may be for a more narrow indication than we expect.

A drug candidate cannot be commercialized until the appropriate regulatory authorities have reviewed and approved the drug candidate. Even if our drug candidates demonstrate safety and efficacy in clinical studies, the regulatory agencies may not complete their review processes in a timely manner, or we may not be able to obtain regulatory approval. Additional delays may result if an FDA Advisory Committee or other regulatory advisory group or authority recommends non-approval or restrictions on approval. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory agency policy during the period of product development, clinical studies and the review process. Regulatory agencies also may approve a drug candidate for fewer or more limited indications than requested or may grant approval subject to the performance of post-marketing studies. In addition, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our drug candidates. Failure to obtain, or a delay in obtaining, regulatory approval to commercialize a drug candidate will impair our ability to generate revenues and harm our business prospects.

Even if we obtain regulatory approval for a drug candidate, our drug candidate will remain subject to regulatory scrutiny.

If our drug candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies and submission of safety, efficacy and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities.

Manufacturers and manufacturing facilities are required to comply with extensive FDA, and comparable foreign regulatory authority, requirements, including ensuring that quality control and manufacturing procedures conform to current Good Manufacturing Practices, or cGMP, regulations. As such, we will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any, BLA or marketing authorization application, or MAA. Accordingly, we and our collaborators and suppliers must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

Any regulatory approvals that we or our collaboration partners receive for our drug candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval or may contain requirements for potentially costly additional clinical trials and surveillance to monitor the safety and efficacy of the drug candidate. We will be required to report certain adverse reactions and production problems, if any, to the FDA and comparable foreign regulatory authorities. Any new legislation addressing drug safety issues could result in delays in product development or commercialization or increased costs to assure compliance. We will have to comply with requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. As such, we are not allowed to promote our products for indications or uses for which they do not have approval. If our drug candidates are approved, we must submit new or supplemental applications and obtain approval for certain changes to the approved products, product labeling or manufacturing process. We could also be asked to conduct post-marketing clinical trials to verify the safety and efficacy of our products in general or in specific patient subsets. An unsuccessful post-marketing study or failure to complete such a study could result in the withdrawal of marketing approval.

If a regulatory agency discovers previously unknown problems with an approved product, such as adverse events of unanticipated severity or frequency or problems with our manufacturing facilities or disagrees with the promotion, marketing or labeling of a product, such regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:

- Issue untitled and warning letters;
- Impose civil or criminal penalties;
- Suspend or withdraw regulatory approval or revoke a license;
- Suspend any of our ongoing clinical trials;
- Refuse to approve pending applications or supplements to approved applications submitted by us;
- Impose restrictions on our operations, including closing our manufacturing facilities; or
- Seize or detain products or require a product recall.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be negatively impacted.

The commercial success of any current or future pharmaceutical products will depend upon the degree of market acceptance by physicians, patients, third-party payors and others in the medical community.

Even with the requisite approvals, the commercial success of our pharmaceutical products will depend in part on the medical community, patients, and third-party payors accepting our pharmaceutical products as medically useful, cost-effective, and safe. Any pharmaceutical product that we or our partners bring to the market may not gain market acceptance by physicians, patients, third-party payors and others in the medical community. The degree of market acceptance of these pharmaceutical products, if approved for commercial sale, will depend on a number of factors, including:

- The effectiveness of our approved drug candidates as compared to currently available products;
- Patient willingness to adopt our approved drug candidates in place of current therapies;
- Our ability to provide acceptable evidence of safety and efficacy;
- Relative convenience and ease of administration;
- The prevalence and severity of any adverse side effects;
- Restrictions on use in combination with other products;
- Availability of alternative treatments;
- Pricing and cost-effectiveness assuming either competitive or potential premium pricing requirements, based on the profile of our drug candidates and target markets;
- Effectiveness of our or our partners' sales and marketing strategy;
- Our ability to obtain sufficient third-party coverage or reimbursement; and
- Potential product liability claims.

Even if a potential product displays a favorable efficacy and safety profile in preclinical and clinical studies, market acceptance of the product will not be known until after it is launched. Our efforts to educate the medical community and third-party payors on the benefits of the pharmaceutical products may require significant resources and may never be successful. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become profitable.

The commercial potential of a pharmaceutical candidate in development is difficult to predict. If the market size for a new drug candidate or technology is significantly smaller than we anticipate, it could significantly and negatively impact our revenue, results of operations and financial condition.

It is very difficult to estimate the commercial potential of pharmaceutical products due to important factors such as safety and efficacy compared to other available technologies or treatments, including changing standards of care, third-party payor reimbursement standards, patient and physician preferences, the availability of competitive alternatives that may emerge either during the long drug development process or after commercial introduction, and the availability of generic versions of our successful drug candidates following approval by government health authorities based on the expiration of regulatory exclusivity or our inability to prevent generic versions from coming to market by asserting our patents. If due to these factors, or others, the market potential for a pharmaceutical product is lower than we anticipated, it could significantly and negatively impact the commercial terms of any collaboration partnership potential for such pharmaceutical product or, if we have already entered into a collaboration for such pharmaceutical product, the revenue potential from royalty and milestone payments could be significantly diminished which would negatively impact our business, financial condition and results of operations.

Failure to obtain or maintain adequate coverage and reimbursement for our drug candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue.

The success of our drug candidates, if approved, depends on the availability of adequate coverage and reimbursement from third-party payors. In addition, because our drug candidates represent new approaches to the treatment of certain diseases, we cannot be sure that coverage and reimbursement will be available for, or accurately estimate the potential revenue from, our drug candidates or assure that coverage and reimbursement will be available for any product that we may develop.

Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors are critical to new product acceptance.

Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs and treatments they will cover and the amount of reimbursement. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

- A covered benefit under its health plan;
- Safe, effective and medically necessary;
- Appropriate for the specific patient;
- Cost-effective; and
- Neither experimental nor investigational.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. As a result, obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our products on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Additionally, third-party payors may not cover, or provide adequate reimbursement for, long-term follow-up evaluations required following the use of our gene-modifying products. Patients are unlikely to use our drug candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our drug candidates. There is significant uncertainty related to insurance coverage and reimbursement of newly approved products. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our drug candidates.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our drug candidates. We expect to experience pricing pressures in connection with the sale of any of our drug candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, cost containment initiatives and additional legislative changes.

We intend to seek approval to market our drug candidates in both the United States and in select foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for our drug candidates, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, the pricing of pharmaceutical products is subject to governmental control and other market regulations which could put pressure on the pricing and usage of our drug candidates. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a drug candidate. In addition, market acceptance and sales of our drug candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for our drug candidates and may be affected by existing and future health care reform measures. Failure to obtain or maintain adequate coverage and reimbursement for our drug candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue.

We may use our financial and human resources to pursue a particular research program or drug candidate and fail to capitalize on programs or drug candidates that may be more profitable or for which there is a greater likelihood of success.

Because we have limited resources, we may forego or delay pursuit of opportunities with certain programs or drug candidates or for indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs for drug candidates may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular drug candidate, we may relinquish valuable rights to that drug candidate through strategic collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such drug candidate, or we may allocate internal resources to a drug candidate in a therapeutic area in which it would have been more advantageous to enter into a partnering arrangement. Failure to pursue opportunities with greater commercial potential or relinquishing valuable rights to drug candidates may adversely impact our business, results of operations and prospects.

We may not be successful in our efforts to identify or discover additional pharmaceutical products.

The success of our business depends primarily upon our ability to identify and develop pharmaceutical products. Although some of our existing pharmaceutical products are currently in clinical development, our research programs may fail to identify other potential pharmaceutical products for clinical development for a number of reasons. Our research methodology may be unsuccessful in identifying potential pharmaceutical products or our potential pharmaceutical products may be shown to have harmful side effects or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval.

If any of these events occur, we may be forced to abandon our development efforts for a program or programs, which would have a material adverse effect on our business and could potentially cause us to cease operations. Research programs to identify new pharmaceutical products require substantial technical, financial and human resources. We may focus our efforts and resources on potential programs or pharmaceutical products that ultimately prove to be unsuccessful. If we are not successful in our efforts to identify or discover additional pharmaceutical products, it could adversely affect our business, results of operations and prospects.

We may fail to obtain orphan drug designations from the FDA for our drug candidates, and even if we obtain such designations, we may be unable to maintain the benefits associated with orphan drug designation, including the potential for market exclusivity.

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug or biologic intended to treat a rare disease or condition, which is defined as one occurring in a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug or biologic will be recovered from sales in the United States. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications, including a full NDA or BLA, to market the same drug or biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or where the manufacturer is unable to assure sufficient product quantity.

OncoHist for AML and XBIO-101 for endometrial cancer have orphan designation in the U.S. While we have not obtained nor have we sought to obtain additional orphan designations for any drug candidate, we believe our products and drug candidates could qualify for additional orphan drug designations for additional indications. We may seek to obtain orphan drug designation for our drug candidates for any qualifying indications they may be approved for in the future. Even if we obtain such designations, we may not be the first to obtain marketing approval of our drug candidate for the orphan-designated indication due to the uncertainties associated with developing pharmaceutical products. In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition. Even after an orphan product is approved, the FDA can subsequently approve the same drug with the same active moiety for the same condition if the FDA concludes that the later drug is safer, more effective or makes a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time of a drug, nor gives the drug any advantage in the regulatory review or approval process. In addition, while we may seek orphan drug designation for our drug candidates, we may never receive such designations.

The market opportunities for our drug candidates may be limited to those patients who are ineligible for or have failed prior treatments and may be small.

Cancer therapies are sometimes characterized as first line, second line or third line, and the FDA often approves new therapies initially only for third line use. When cancer is detected early enough, first line therapy is sometimes adequate to cure the cancer or prolong life without a cure. Whenever first line therapy, usually chemotherapy, hormone therapy, surgery or a combination of these, proves unsuccessful, second line therapy may be administered. Second line therapies often consist of more chemotherapy, radiation, antibody drugs, tumor targeted small molecules or a combination of these. Third line therapies can include bone marrow transplantation, antibody and small molecule targeted therapies, more invasive forms of surgery and new technologies. In markets with approved therapies, we expect to initially seek approval of our drug candidates as a later stage therapy for patients who have failed other approved treatments. Subsequently, for those drugs that prove to be sufficiently beneficial, if any, we would expect to seek approval as a second line therapy and potentially as a first line therapy, but there is no guarantee that our drug candidates, even if approved, would be approved for second line or first line therapy. In addition, we may have to conduct additional clinical trials prior to gaining approval for second line or first line therapy.

Our projections of both the number of people who have the cancers we are targeting, as well as the subset of people with these cancers in a position to receive later stage therapy and who have the potential to benefit from treatment with our drug candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations or market research and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these cancers. The number of patients may turn out to be lower than expected. In addition, the potentially addressable patient population for our drug candidates may be limited or may not be amenable to treatment with our drug candidates. Even if we obtain significant market share for our drug candidates, we may never achieve profitability without obtaining regulatory approval for additional indications, including use as a first or second line therapy, which may adversely affect our business and results of operations.

Healthcare legislative reform measures may have a material adverse effect on our business and results of operations.

In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory enactments in recent years that change the healthcare system in ways that could impact our future ability to sell our drug candidates profitably.

Furthermore, there have been and continue to be a number of initiatives at the federal and state level that seek to reduce healthcare costs. Most significantly, in March 2010, the Patient Protection and Affordable Health Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, was signed into law, which includes measures that significantly change the way healthcare is financed by both governmental and private insurers. In January 2017, Congress voted to adopt a budget resolution for fiscal year 2017, or the Budget Resolution, that authorizes the implementation of legislation that would repeal portions of the ACA. Further, on January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. Congress also could consider subsequent legislation to replace elements of the ACA that are repealed.

Laws and other reform and cost containment measures that may be proposed and adopted in the future, remain uncertain, but may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on our future customers and accordingly, our ability to generate revenue, attain profitability, or commercialize our products.

Risks Related to Our Reliance on Third-Parties

If conflicts arise between us and our collaborators or strategic partners, these parties may act in their self-interest, which may limit our ability to implement our strategies.

If conflicts arise between our corporate or academic collaborators or strategic partners and us, the other party may act in its self-interest, which may limit our ability to implement our strategies. Some of our academic collaborators and strategic partners are conducting multiple product development efforts within each area that is the subject of the collaboration with us. Our collaborators or strategic partners, however, may develop, either alone or with others, products in related fields that are competitive with the products or potential products that are the subject of these collaborations. Competing products, either developed by the collaborators or strategic partners or to which the collaborators or strategic partners have rights, may result in the withdrawal of partner support for our drug candidates.

Some of our collaborators or strategic partners could also become our competitors in the future. Our collaborators or strategic partners could develop competing products, preclude us from entering into collaborations with their competitors, fail to obtain timely regulatory approvals, terminate their agreements with us prematurely, or fail to devote sufficient resources to the development and commercialization of products. Any of these developments could harm our product development efforts, which may adversely affect our business, results of operations and prospects.

In addition to our own clinical trials, we expect to rely on third-parties to conduct, supervise and monitor our clinical studies, and if these third-parties perform in an unsatisfactory manner, it may harm our business.

In addition to our own clinical trials, we expect to rely on CROs, clinical investigators and clinical study sites to ensure our clinical studies are conducted properly and on time. While we will have agreements governing their activities, we will have limited influence over their actual performance. We will control only certain aspects of our CROs' activities. Nevertheless, we will be responsible for ensuring that each of our clinical studies is conducted in accordance with the applicable protocol, legal, and regulatory requirements and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities.

We, clinical investigators and our CROs are required to comply with the FDA's GCPs for conducting, recording and reporting the results of clinical trials to assure that the data and reported results are credible and accurate and that the rights, integrity and confidentiality of clinical trial participants are protected. The FDA enforces these GCPs through periodic inspections of study sponsors, principal investigators and clinical trial sites. If we or our CROs or the clinical investigators fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving any marketing applications. Upon inspection, the FDA may determine that our clinical trials did not comply with GCPs. In addition, our future clinical trials will require a sufficient number of test subjects to evaluate the safety and efficacy of our drug candidates. Accordingly, if our CROs or clinical investigators fail to comply with these regulations or fail to recruit a sufficient number of patients, we may be required to repeat such clinical trials, which would delay the regulatory approval process.

Our CROs are not our employees, and we are therefore unable to directly monitor whether or not they devote sufficient time and resources to our clinical and nonclinical programs, which must be conducted in accordance with GCPs and GLPs, respectively. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical studies or other drug development activities that could harm our competitive position. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements, or for any other reasons, our clinical studies may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize our pharmaceutical products. As a result, our financial results and the commercial prospects for our pharmaceutical products would be harmed, our costs could increase, and our ability to generate revenues could be delayed.

We may also rely on other third-parties to store and distribute our products for any clinical studies that we may conduct. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our pharmaceutical products or commercialization of our products, if approved, producing additional losses and depriving us of potential product revenue.

Our collaborators or strategic partners may decide to adopt alternative technologies or may be unable to develop commercially viable products with our technology, which would negatively impact our revenues and our strategy to develop these products.

Our collaborators or strategic partners may adopt alternative technologies, which could decrease the marketability of our products. Additionally, because our current or future collaborators or strategic partners are likely to be working on more than one development project, they could choose to shift their resources to projects other than those they are working on with us. If they do so, this would delay our ability to test our technology and would delay or terminate the development of potential products based on our platforms. Further, our collaborators and strategic partners may elect not to develop products arising out of our collaborative and strategic partnering arrangements or to devote sufficient resources to the development, manufacturing, marketing or sale of these products. The failure to develop and commercialize a drug candidate pursuant to our agreements with our current or future collaborator would prevent us from receiving future milestone and royalty payments which would negatively impact our revenues.

We may seek to establish additional collaborations and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans.

Our drug candidate development programs and the potential commercialization of our drug candidates will require substantial additional cash to fund expenses. For some of our drug candidates, we may decide to collaborate with additional pharmaceutical and biotechnology companies for the development and potential commercialization of those drug candidates.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for any additional collaborations will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by FDA or similar regulatory authorities outside the United States, the potential market for the subject drug candidate, the costs and complexities of manufacturing and delivering such drug candidate to patients, the potential of competing drugs, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. The collaborator may also consider alternative drug candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our drug candidate. The terms of any additional collaborations or other arrangements that we may establish may not be favorable to us.

We may also be restricted under existing collaboration agreements from entering into future agreements on certain terms with potential collaborators. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate additional collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the drug candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our drug candidates or bring them to market and generate product revenue.

If we enter into one or more collaborations, we may be required to relinquish important rights to and control over the development of our drug candidates or otherwise be subject to unfavorable terms.

Any future collaborations we enter into could subject us to a number of risks, including:

- We may not be able to control the amount and timing of resources that our collaborators devote to the development or commercialization of our drug candidates;
- Collaborators may delay clinical trials, provide insufficient funding, terminate a clinical trial or abandon a drug candidate, repeat or conduct new clinical trials or require a new version of a drug candidate for clinical testing;
- Collaborators may not pursue further development and commercialization of products resulting from the strategic partnering arrangement or may elect to discontinue research and development programs;
- Collaborators may not commit adequate resources to the marketing and distribution of our drug candidates, limiting our potential revenues from these products;
- Disputes may arise between us and our collaborators that result in the delay or termination of the research, development or commercialization of our drug candidates or that result in costly litigation or arbitration that diverts management's attention and consumes resources;
- Collaborators may experience financial difficulties;
- Collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in a manner that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- Business combinations or significant changes in a collaborator's business strategy may also adversely affect a collaborator's willingness or ability to complete its obligations under any arrangement;
- Collaborators could decide to move forward with a competing drug candidate developed either independently or in collaboration with others, including our competitors; and
- Collaborators could terminate the arrangement or allow it to expire, which would delay the development and may increase the cost of developing our drug candidates.

Our contract manufacturers are subject to significant regulation with respect to manufacturing our products. The manufacturing facilities on which we rely may not continue to meet regulatory requirements and have limited capacity.

We currently have relationships with a limited number of suppliers for the manufacturing of our pharmaceutical products. Each supplier may require licenses to manufacture components if such processes are not owned by the supplier or in the public domain and we may be unable to transfer or sublicense the intellectual property rights we may have with respect to such activities.

All entities involved in the preparation of pharmaceutical products for clinical studies or commercial sale, including our existing contract manufacturers for our drug candidates, are subject to extensive regulation. Components of a finished pharmaceutical product approved for commercial sale or used in late-stage clinical studies must be manufactured in accordance with cGMP. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of our pharmaceutical products that may not be detectable in final product testing. Our contract manufacturers must supply all necessary documentation in support of an NDA or BLA on a timely basis and must adhere to the FDA's GLP, and cGMP regulations enforced by the FDA through its facilities inspection program. The facilities and quality systems of some or all of our third-party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our pharmaceutical products or any of our other potential products. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our pharmaceutical products or our other potential products or the associated quality systems for compliance with the regulations applicable to the activities being conducted. If these facilities do not pass a pre-approval plant inspection, FDA approval of the products will not be granted.

The regulatory authorities also may, at any time following approval of a product for sale, audit the manufacturing facilities of our third-party contractors. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and/or time-consuming for us or a third-party to implement and that may include the temporary or permanent suspension of a clinical study or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon third-parties with whom we contract could materially harm our business.

If our third-party manufacturers fail to maintain regulatory compliance, the FDA can impose regulatory sanctions including, among other things, refusal to approve a pending application for a drug candidate, or revocation of a pre-existing approval. As a result, our business, financial condition and results of operations may be materially harmed.

Additionally, if supply from one approved manufacturer is interrupted, there could be a significant disruption in commercial supply. The number of manufacturers with the necessary manufacturing capabilities is limited. In addition, an alternative manufacturer would need to be qualified through an NDA or BLA supplement which could result in further delay. The regulatory agencies may also require additional studies if a new manufacturer is relied upon for commercial production. Switching manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines, which could materially harm our business and results of operations.

These factors could cause the delay of clinical studies, regulatory submissions, required approvals or commercialization of our pharmaceutical products, cause us to incur higher costs and prevent us from commercializing our products successfully. Furthermore, if our suppliers fail to meet contractual requirements, and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical studies may be delayed or we could lose potential revenue, which could materially harm our business and results of operations.

We have no manufacturing, sales, marketing or distribution capabilities, and we may have to invest significant resources to develop these capabilities.

We have no internal manufacturing capabilities. As a result, for manufacturing we depend on third-party manufacturers, including Kevelt, Pharmsynthez and the Serum Institute, which in turn may rely upon third-parties to manufacture our products. Although our strategy is based on leveraging the ability of collaboration partners to develop and manufacture our products for commercialization in the pharmaceutical marketplace, we will be dependent on collaborations with drug development and manufacturing collaborators. If we are not able to maintain existing collaborative arrangements or establish new arrangements on commercially acceptable terms, we would be required to undertake product manufacturing and development activities at our own expense. This would increase our capital requirements or require us to limit the scope of our development activities. Moreover, we have limited or no experience in conducting full scale bioequivalence or other clinical studies, preparing and submitting regulatory applications, and distributing and marketing pharmaceutical products and as such we are reliant on contract parties for such efforts. We may not be able to enter into collaborations or hire consultants or external service providers to assist us in sales, marketing and distribution functions on acceptable financial terms or at all.

If any of our developmental collaborators breach or terminate their agreements with us or otherwise fail to conduct their collaborative activities in a timely manner, the pre-clinical and/or clinical development and/or commercialization of our pharmaceutical products will be delayed and we would be required to devote additional resources to product development and commercialization or terminate certain development programs. Also, a license relationship may be terminated at the discretion of our collaborator, or at the end of contract terms, and in some cases with only limited notice to us. The termination of the collaborative arrangement could have a material adverse effect on our business, financial condition and results of operations. There also can be no assurance that disputes will not arise with respect to the ownership of rights to any technology developed with third-parties. These and other possible disagreements with collaborators could lead to delays in the development or commercialization of our pharmaceutical products or could result in litigation or arbitration, which could be time consuming and expensive and could have a material adverse effect on our business, financial condition and results of operations. Even if we decide to perform clinical trials, sales, marketing and distribution functions ourselves, we could face a number of additional related risks, including:

- we may not be able to attract clinical investigators and build effective clinical trials, or a solid marketing department or sales force;
- the cost of establishing an internal clinical trials program, marketing department or sales force may exceed our available financial resources and the revenue generated by XBIO-101, if approved, or any other pharmaceutical products that we may develop, in-license or acquire; and
- our direct sales and marketing efforts may not be successful.

Any failure to perform such activities could have a material adverse effect on our business, financial condition and results of our operations.

Our reliance on third-parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Because we rely on third-parties to manufacture our pharmaceutical products, and because we collaborate with various organizations and academic institutions on the development of our pharmaceutical products, we must, at times, share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third-parties to use or disclose our confidential information, such as trade secrets. Despite the contractual provisions employed when working with third-parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business.

In addition, these agreements typically restrict the ability of our collaborators, advisors, employees and consultants to publish data potentially relating to our trade secrets. Our academic collaborators typically have rights to publish data, provided that we are notified in advance and may delay publication for a specified time in order to secure our intellectual property rights arising from the collaboration. In other cases, publication rights are controlled exclusively by us, although in some cases we may share these rights with other parties. We may also conduct joint research and development programs that may require us to share trade secrets under the terms of our research and development partnerships or similar agreements. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of these agreements, independent development or publication of information including our trade secrets in cases where we do not have proprietary or otherwise protected rights at the time of publication. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

Risks Related to Our Intellectual Property

If we fail to adequately protect or enforce our intellectual property rights, we may be unable to operate effectively.

Our success and ability to compete are substantially dependent on our patents, proprietary formulations and trademarks. Although we believe that the patents and associated trademarks and licenses are valid, there can be no assurance that they will not be challenged and subsequently invalidated and/or canceled. The invalidation or cancellation of any one or all of the patents or trademarks would significantly damage our commercial prospects. Further, we may find it necessary to legally challenge parties infringing our patents or trademarks or licensed trademarks to enforce our rights thereto. There can be no assurance that any of the patents would ultimately be held valid or that efforts to defend any of the patents, trade secrets, know-how or other IP rights would be successful.

The patent positions of pharmaceutical and biotechnology companies, such as ours, are uncertain and involve complex legal and factual issues. We own numerous U.S. and foreign patents and a number of pending patent applications that cover various aspects of our drug candidates and technologies. There can be no assurance that patents that have been issued will be held valid and enforceable in a court of law. Even for patents that are held valid and enforceable, the legal process associated with obtaining such a judgment is time consuming and costly. Additionally, issued patents can be subject to opposition or other proceedings that can result in the revocation of the patent or maintenance of the patent in amended form (and potentially in a form that renders the patent without commercially relevant and/or broad coverage). Further, our competitors may be able to circumvent and otherwise design around our patents. Even if a patent is issued and enforceable, because development and commercialization of pharmaceutical products can be subject to substantial delays, patents may expire early and provide only a short period of protection, if any, following the commercialization of a product encompassed by our patents. We may have to participate in interference proceedings declared by the USPTO, which could result in a loss of the patent and/or substantial cost to us.

We have filed patent applications and plan to file additional patent applications, covering various aspects of our drug candidates and technologies. There can be no assurance that the patent applications for which we apply would actually be issued as patents, or do so with commercially relevant and/or broad coverage. The coverage claimed in a patent application can be significantly reduced before the patent is issued. The scope of our claim coverage can be critical to our ability to enter into licensing transactions with third-parties and our right to receive royalties from our collaboration partnerships. Since publication of discoveries in scientific or patent literature often lags behind the date of such discoveries, we cannot be certain that we were the first inventor of inventions covered by our patents or patent applications. In addition, there is no guarantee that we will be the first to file a patent application directed to an invention.

An adverse outcome in any judicial proceeding involving IP, including patents, could subject us to significant liabilities to third-parties, require disputed rights to be licensed from or to third-parties or require us to cease using the technology in dispute. In those instances where we seek an IP license from another, we may not be able to obtain the license on a commercially reasonable basis, if at all, thereby raising concerns on our ability to freely commercialize our technologies and/or products. It is also possible that we or our licensors or licensees will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from or license to third parties and are reliant on our licensors or licensees. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. If our current or future licensors or licensees fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our licensors or licensees are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised.

Failure to adequately protect or enforce our intellectual property rights could have a material adverse impact on our business, results of operations and prospects.

Issued patents covering our drug candidates could be found invalid or unenforceable if challenged in court.

If we or one of our licensing partners initiated legal proceedings against a third-party to enforce a patent covering one of our drug candidates, the defendant could counterclaim that the patent covering our drug candidate is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third-parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover our drug candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our drug candidates. Such a loss of patent protection would have a material adverse impact on our business.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on drug candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third-parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our inventions in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third-parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Failure to adequately protect our intellectual property rights throughout the world could have a material adverse impact on our business, results of operations and prospects.

If we infringe on the intellectual property rights of others, our business and profitability may be adversely affected.

Our commercial success will also depend, in part, on us and our collaborative partners not infringing on the patents or proprietary rights of others. There can be no assurance that the technologies and products used or developed by our collaborative partners and marketed and sold by us will not infringe such rights. If such infringement occurs and neither we nor our collaborative partner is able to obtain a license from the relevant third-party, we will not be able to continue the development, manufacture, use, or sale of any such infringing technology or product. There can be no assurance that necessary licenses to third-party technology will be available at all, or on commercially reasonable terms. In some cases, litigation or other proceedings may be necessary to defend against or assert claims of infringement or to determine the scope and validity of the proprietary rights of third-parties. Any potential litigation could result in substantial costs to, and diversion of, our resources and could have a material and adverse impact on us. An adverse outcome in any such litigation or proceeding could subject us to significant liabilities, require us to cease using the subject technology or require us to license the subject technology from the third-party, all of which could have a material adverse effect on our business.

If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third-parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

We are a party to a number of intellectual property license agreements that are important to our business and we expect to enter into additional license agreements in the future. Our existing license agreements impose, and we expect that future license agreements will impose, various diligence, milestone payment, royalty and other obligations on us. If we fail to comply with our obligations under these agreements, or we are subject to a bankruptcy, the licensor may have the right to terminate the license, in which event we would not be able to market products covered by the license.

We may need to obtain licenses from third-parties to advance our research, and we have done so from time to time. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we may be required to expend significant time and resources to develop or license replacement technology. If we are unable to do so, we may be unable to develop the affected drug candidates, which could harm our business significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our current drug candidates or future products, resulting in either an injunction prohibiting the sales, or, with respect to the sales, an obligation on our part to pay royalties and/or other forms of compensation to third-parties.

In many cases, patent prosecution of our licensed technology is controlled solely by the licensor. If our licensors fail to obtain and maintain patent or other protection for the proprietary intellectual property we license from them, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, and our competitors could market competing products using the intellectual property. In certain cases, we control the prosecution of patents resulting from licensed technology. In the event we breach any of our obligations related to such prosecution, we may incur significant liability to our licensing partners. Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues and is complicated by the rapid pace of scientific discovery in our industry. Disputes may arise regarding intellectual property subject to a licensing agreement, including:

- The scope of rights granted under the license agreement and other interpretation-related issues;
- The extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- The sublicensing of patent and other rights under our collaborative development relationships;
- Our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- The ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- The priority of invention of patented technology.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected drug candidates, which could have a material adverse effect on our business.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid, is unenforceable and/or is not infringed, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.

Interference proceedings provoked by third-parties or brought by us may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock underlying the units.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biotechnology industry involve both technological and legal complexity and is, therefore, costly, time-consuming and inherently uncertain. In addition, the United States has recently enacted and is currently implementing wide-ranging patent reform legislation. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our and our licensors' patent applications and the enforcement or defense of our or our licensors' issued patents. Provisions of the Leahy-Smith America Invents Act, or the Leahy-Smith Act, adopted in September 2011, which includes a number of significant changes to U.S. patent law, are still being implemented through the adoption of new regulations. The Leahy-Smith Act and its implementation, in addition to any new regulation, could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third-parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

We employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and independent contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of any of our employee's former employers or other third-parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely impact our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We may also be subject to claims that former employees, collaborators or other third-parties have an ownership interest in our patents or other intellectual property. We may have in the future ownership disputes arising, for example, from conflicting obligations of consultants or others who are involved in developing our drug candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Our inability to protect our confidential information and trade secrets would harm our business and competitive position.

In addition to seeking patents for some of our technology and products, 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 both within and outside the United States may be less willing or unwilling to protect trade secrets. If a competitor lawfully obtained or independently developed any of our trade secrets, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position and our business.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and/or applications. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. Non-compliance may result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market and this circumstance would have a material adverse effect on our business.

Risks Related to Our Business Operations

We operate in an extremely competitive environment and there can be no assurances that competing technologies would not harm our business development.

We are engaged in a rapidly evolving field. Competition from numerous pharmaceutical companies is intense and expected to increase including for oncology orphans: Galena BioPharma, Merck Sharp & Dohme; Immunogen, Inc., Immunomedics, Inc., Genentech, Macrogenics, Genmab, Incyte Corporation, Eisai Inc., Bayer, ArQule, AstraZeneca; Novartis, Daiichi Sankyo Inc., GlaxoSmithKline, Advenchen Laboratories LLC, Stemline Therapeutics, Inc., Rexahn Pharmaceuticals, Inc. and Peregrine Pharmaceuticals, Inc.; and for protein delivery products: Nektar's PEG technology, Flamel's Medusa platform offering, a hydrogel depot formulation, Versartis' XTEN technology utilizing a recombinant polypeptide fusion protein, nanoparticle technology from Alkermes, Durect Corp's long-acting technology, Debiopharm Group's drug delivery based on polylactic-co-glycolic acid (PLGA), and Halozyme's ENHANZE drug delivery technology; as well as research and academic institutions. The large and rapidly growing market for liposomal drugs and oncology treatments is likely to attract new entrants. Numerous biotechnology and pharmaceutical companies are focused on developing new liposomal drug delivery systems and cancer treatments. Many, if not all, of these companies have greater financial and other resources and development capabilities than we do. Many of our competitors also have greater collective experience in undertaking pre-clinical and clinical testing of products, obtaining regulatory approvals and manufacturing and marketing prescription pharmaceutical products. There can be no assurance that our under-development drug candidates will be more effective or achieve greater market acceptance than competitive products, or that our competitors will not succeed in developing products and technologies that are more effective than those being developed by us or that would render our products and technologies less competitive or obsolete. Additionally, there can be no assurance that the development by others of new or improved drugs will not make our pharmaceutical products superfluous or obsolete.

We are a party to collaboration agreements and other significant agreements which contain complex commercial terms that could result in disputes, litigation or indemnification liability that could adversely affect our business, results of operations and financial condition.

We currently derive, and expect to derive in the foreseeable future, all of our revenue from collaboration agreements with biotechnology and pharmaceutical companies. These collaboration agreements contain complex commercial terms, including:

- Clinical development and commercialization obligations that are based on certain commercial reasonableness performance standards that can often be difficult to enforce if disputes arise as to adequacy of our partner's performance;
- Research and development performance and reimbursement obligations for our personnel and other resources allocated to partnered drug candidate development programs;
- Clinical and commercial manufacturing agreements, some of which are priced on an actual cost basis for products supplied by us to our partners with complicated cost allocation formulas and methodologies;
- Intellectual property ownership allocation between us and our partners for improvements and new inventions developed during the course of the collaboration;
- Royalties on drug sales based on a number of complex variables, including net sales calculations, geography, scope of patent claim coverage, patent life, generic competitors, bundled pricing and other factors; and
- Indemnity obligations for intellectual property infringement, product liability and certain other claims.

From time to time, we have informal dispute resolution discussions with third-parties regarding the appropriate interpretation of the complex commercial terms contained in our agreements. One or more disputes may arise or escalate in the future regarding our collaboration agreements, transaction documents, or third-party license agreements that may ultimately result in costly litigation and unfavorable interpretation of contract terms, which would have a material adverse effect on our business, financial condition and results of operations.

Governments may impose price controls, which may adversely affect our future profitability.

We intend to seek approval to market our drug candidates in both the United States and in foreign jurisdictions. In some foreign countries and jurisdictions, particularly in the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a drug candidate. To obtain reimbursement or pricing approval in some countries, we may be required to conduct clinical trials to compare the cost effectiveness of our drug candidates to other available therapies, which is time consuming and costly. If reimbursement of our future products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability.

Write-offs related to the impairments of our long-lived assets, including goodwill and indefinite-lived intangible assets, and other non-cash charges such as share-based payments may adversely impact our results of operations.

We may incur significant non-cash charges related to impairments of our long-lived assets, including goodwill and indefinite-lived intangible assets. Although we did not record any such charges during 2017, we are required to perform periodic impairment reviews of those assets at least annually. The carrying value of goodwill on our balance sheet that is subject to impairment reviews was approximately $3.3 million at December 31, 2017 and December 31, 2016 and the carrying value of our indefinite-lived assets was $9.2 million at December 31, 2017 and December 31, 2016. To the extent future reviews conclude that the expected future cash flows generated from our business activities are not sufficient to recover the carrying value of these assets, we will be required to measure and record an impairment charge to write-down these assets to their realizable values and those impairment charges could be equal to the entire carrying value.

We completed our last review during the fourth quarter of 2017 and determined that goodwill and indefinite-lived intangible assets were not impaired as of December 31, 2017. However, there can be no assurance that upon completion of subsequent reviews a material impairment charge will not be recorded. If future periodic reviews determine that our assets are impaired and a write-down is required, it will adversely impact our operating results.

In addition, we recorded non-cash charges of approximately $1.8 million and $3.2 million for share-based payments during the years ended December 31, 2017 and 2016, respectively. In the future, this amount could fluctuate materially as the Company expects to continue to issue share-based payments awards.

Potential new accounting standards or legislative actions may adversely impact our future financial position or results of operations.

Future changes in financial accounting standards may cause adverse, unexpected fluctuations in the timing of the recognition of revenues or expenses, and may affect our financial position or results of operations. New standards may occur in the future and may cause us to be required to make changes in our accounting policies. Compliance with changing regulation of corporate governance and public disclosure may result in additional expenses. Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, new SEC regulations, Public Company Accounting Oversight Board, or PCAOB, standards and NASDAQ rules, are creating uncertainty for companies such as ours and insurance, accounting and auditing costs are high as a result of this uncertainty and other factors.

We are committed to maintaining high standards of corporate governance and public disclosure. As a result, we intend to invest all reasonably necessary resources to comply with evolving standards, and this investment may result in increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities.

Varying interpretations of existing standards and rules have occurred with frequency and may cause us to have to restate previously reported result of operations.

Varying interpretations of existing standards of accounting policies or accounting treatments of existing transactions may cause us to have to restate previously reported result of operations.

For example, in January 2014 we completed a transaction that we determined to be a reverse merger business combination. We allocated the purchase price consideration to the assets acquired and liabilities assumed at their estimated fair values as of the date of acquisition. Our determination that the transaction met the criteria for a business combination was based on our best knowledge of the facts and circumstances surrounding the transaction, and required the application of our judgment. Changes to this determination would result in the transaction to be accounted for as a recapitalization, with no goodwill recorded, which could cause a material change in our reported results of operations and could cause the Company to have to amend prior periodic or other filings with the SEC, at further expense to the Company. We may be subject to similar varying interpretations of existing standards of accounting policies or accounting treatments in the future.

In addition, we do not consider the Company to be a development stage entity for financial reporting presentation purposes. A determination that the Company is a development stage entity could cause a material change in our reported results of operations and could cause the Company to have to amend prior periodic or other filings with the SEC, at further expense to the Company.

Tax reform may significantly affect the Company and its stockholders.

On December 22, 2017, the Tax Cuts and Jobs Act ("TCJA"), which significantly reforms the Code, was signed into law. The TCJA, among other things, includes changes to U.S. federal tax rates, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitations of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitations of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, modifying or repealing many business deductions and credits and putting into effect the migration from a "worldwide" system of taxation to a territorial system. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the new federal tax law is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will adjust their policies in response to the newly enacted federal tax law. The impact of this tax reform on holders of our common stock is uncertain and could be adverse.

Our future success depends on our ability to retain key employees, consultants and advisors and to attract, retain and motivate qualified personnel.

We are highly dependent on principal members of our executive team and key employees, the loss of whose services may adversely impact the achievement of our objectives. Recruiting and retaining other qualified employees, consultants and advisors for our business, including scientific and technical personnel, will also be critical to our success. There is currently a shortage of skilled executives in our industry, which is likely to continue. As a result, competition for skilled personnel is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for individuals with similar skill sets. In addition, failure to succeed in preclinical or clinical studies may make it more challenging to recruit and retain qualified personnel. The inability to recruit or loss of the services of any executive, key employee, consultant or advisor may impede the progress of our research and development objectives.

We will need to expand our organization and we may experience difficulties in managing this growth, which could disrupt our operations.

As of December 31, 2017, we had five full-time employees. As we mature, we may need to expand our full-time employee base and to hire more consultants and contractors. Our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees, all of which may have a material adverse effect on our business, results of operations and prospects. Any future growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of additional drug candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow revenues could be reduced, and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize drug candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth.

Our employees, principal investigators, consultants and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants and commercial partners. Misconduct by these parties could include intentional failures to comply with the regulations of the FDA and non-U.S. regulators, provide accurate information to the FDA and non-U.S. regulators, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct could also involve the improper use of information obtained in the course of clinical studies, which could result in regulatory sanctions and cause serious harm to our reputation or could cause regulatory agencies not to approve our drug candidates. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

We face potential product liability, and, if successful claims are brought against us, we may incur substantial liability and costs. If the use of our drug candidates harms patients, or is perceived to harm patients even when such harm is unrelated to our drug candidates, our regulatory approvals could be revoked or otherwise negatively impacted and we could be subject to costly and damaging product liability claims.

The use of our drug candidates in clinical studies and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our products. There is a risk that our drug candidates may induce adverse events. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- Impairment of our business reputation;
- Withdrawal of clinical study participants;
- Costs due to related litigation;
- Distraction of management's attention from our primary business;
- Substantial monetary awards to patients or other claimants;
- The inability to commercialize our drug candidates; and
- Decreased demand for our drug candidates, if approved for commercial sale,

all of which may have a material adverse effect on our business, results of operations and prospects.

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, including 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.

The workers' compensation insurance we maintain to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials or other work-related injuries may not provide adequate coverage against potential liabilities. 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, which may have material adverse effect on our business and results of operations.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the Exchange Act. Any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected, which may have material adverse effect on our business and results of operations.

Failure in our information technology systems, including by cybersecurity attacks or other data security incidents, could significantly disrupt our operations.

Our operations depend, in part, on the continued performance of our information technology systems. Our information technology systems are potentially vulnerable to physical or electronic break-ins, computer viruses and similar disruptions. Failure of our information technology systems could adversely affect our business, profitability and financial condition.

A successful cybersecurity attack or other data security incident could result in the misappropriation and/or loss of confidential or personal information, create system interruptions, or deploy malicious software that attacks our systems. It is possible that a cybersecurity attack might not be noticed for some period of time. The occurrence of a cybersecurity attack or incident could result in business interruptions from the disruption of our information technology systems, or negative publicity resulting in reputational damage with our clinical trial participants, customers, stockholders and other stakeholders and/or increased costs to prevent, respond to or mitigate cybersecurity events. In addition, the unauthorized dissemination of sensitive personal information or proprietary or confidential information could expose us or other third-parties to regulatory fines or penalties, litigation and potential liability, or otherwise harm our business.

Risks Related to Investment in Our Securities

An active, liquid and orderly market for our common stock may not develop.

Our common stock trades on The NASDAQ Capital Markets. An active trading market for our common stock may never develop or be sustained. If an active market for our common stock does not continue to develop or is not sustained, it may be difficult for investors in our common stock to sell shares without depressing the market price for the shares or to sell the shares at all. An inactive market may also impair our ability to raise capital by selling common stock and may impair our ability to acquire other businesses, applications or technologies using our common stock as consideration, which, in turn, could materially adversely affect our business.

The market price of our stock may be highly volatile, and you may not be able to sell shares of our stock.

Companies trading in the stock market in general have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our stock, regardless of our actual operating performance.

The market price of our stock may be volatile. Our stock price could be subject to wide fluctuations in response to a variety of factors, including the following:

- Adverse results or delays in pre-clinical or clinical studies;
- Inability to obtain additional funding;
- Any delay in filing an IND or BLA for any of our drug candidates and any adverse development or perceived adverse development with respect to the FDA's review of that IND or BLA;
- Failure to develop successfully our drug candidates;
- Failure to maintain our existing strategic collaborations or enter into new collaborations;
- Failure by us or our licensors and strategic collaboration partners to prosecute, maintain or enforce our intellectual property rights;
- Changes in laws or regulations applicable to future products;
- Inability to obtain adequate product supply for our drug candidates or the inability to do so at acceptable prices;
- Adverse regulatory decisions;
- Introduction of new products, services or technologies by our competitors;
- Failure to meet or exceed financial projections we may provide to the public;
- Failure to meet or exceed the financial projections of the investment community;
- The perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- Announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us, our strategic collaboration partner or our competitors;
- Disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- Additions or departures of key scientific or management personnel;
- Significant lawsuits, including patent or stockholder litigation;
- Changes in the market valuations of similar companies;
- Sales of our common stock by us or our stockholders in the future; and
- Trading volume of our common stock.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

As of February 12, 2018, our executive officers, directors, affiliates and other principal stockholders beneficially own approximately 79.1% of our outstanding common stock. Therefore, these stockholders will have the ability to influence us through their ownership positions. Further, our majority stockholder, Pharmsynthez, has beneficial ownership of approximately 7.9 million shares of common stock. These shares represent ownership of approximately 70.2% of our common stock as of February 12, 2018. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders, acting together, may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may believe are in your best interest as one of our stockholders.

We have entered into several agreements with our major stockholders.

We have entered into several agreements with our major stockholders. These arrangements may not have been negotiated at arm's length and may contain terms and conditions that are not in our best interest and would not otherwise be applicable if we entered into arrangements with a third-party not affiliated with us. Although we did, and will, attempt to negotiate agreements at arm's length, some of the agreement parties may be considered affiliates of ours, which may result in conflicts of interest.

Our preferred stock has rights, preferences and privileges that are not held by, and are preferential to, the rights of our common stockholders, which could result in the interests of the holders of our preferred stock differing from those of our common stockholders.

The holders of our preferred stock have the right to receive a liquidation preference entitling them to be paid out of our assets available for distribution to stockholders before any payment may be made to holders of any common stock or any series of preferred stock ranked junior to such class of preferred stock. The existence of a liquidation preference may reduce the value of our common stock, make it harder for us to sell shares of common stock in offerings in the future, or prevent or delay a change of control. Additionally, each share of preferred stock is convertible into one share of common stock, subject to certain adjustments, which may cause substantial dilution to our common stockholders. The preferential rights could result in divergent interests between the holders of shares of preferred stock and holders of our common stock. In addition, our majority shareholder, Pharmsynthez holds shares consisting of the majority of our Series B preferred stock and all of our Series A preferred stock. The interests of these preferred holders may differ from the interests of our security holders as a whole.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because pharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

We do not intend to pay dividends on our common stock or preferred stock so any returns will be limited to the value of our stock.

We have never declared or paid any cash dividends on our common stock or preferred stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to common or preferred stockholders will therefore be limited to the appreciation of their stock.

ITEM 1B – UNRESOLVED STAFF COMMENTS

None.

ITEM 2 – PROPERTIES

We occupy a facility consisting of approximately 4,000 square feet in the Ledgemont Technology Center in Lexington, Massachusetts. The premises are divided into approximately 50% laboratory and 50% office space and are leased by our subsidiary, Xenetic Bioscience, Incorporated. The lease provides for an initial term of 61 months which commenced in January 2014 with an extension option of one additional five-year term. We believe that this space is adequate for our current needs and that, if additional space is required, it can be obtained at commercially reasonable terms either within the Ledgemont Technology Center or nearby.

In addition, we lease 450 sq. ft. of office space in Miami, Florida. The lease provided for an initial term of 12 months, which commenced on December 1, 2016, and was extended for an additional two years through November 30, 2019. We believe that this space is adequate for our current needs and that, if additional space is required, it can be obtained at commercially reasonable terms either within its current space or nearby.

ITEM 3 – LEGAL PROCEEDINGS

From time to time, we may be a party to litigation and subject to claims incident to the ordinary course of business. Although the results of litigation and claims cannot be predicted with certainty, we currently believe that the final outcome of these ordinary course matters will not have a material adverse effect on our business. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

There are no matters, as of December 31, 2017, that, in the opinion of management, might have a material adverse effect on our financial position, results of operation or cash flows.

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

Since November 7, 2016, our common stock has been listed for trading on The NASDAQ Capital Market under the symbol, "XBIO." From January 2014 through November 4, 2016, our common stock was quoted on the OTCQB operated by the OTC Markets Group, Inc. under the same symbol.

The following table sets forth the range of high and low prices for our common stock for each of the periods indicated as reported by the OTCQB and The NASDAQ Capital Market, as applicable. The OTCQB quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not necessarily represent actual transactions. The prices have been adjusted to reflect the 1:33 reverse stock split completed on June 1, 2016.

Year Ended December 31, 2016	High Price	Low Price
1st Quarter Ended March 31, 2016*	$ 17.00	$ 6.80
2nd Quarter Ended June 30, 2016*	10.23	5.00
3rd Quarter Ended September 30, 2016*	5.35	3.30
4th Quarter Ended December 31, 2016 (through November 6, 2016)*	4.75	4.00
4th Quarter Ended December 31, 2016 (after November 6, 2016)	5.70	3.31
Year Ended December 31, 2017		
1st Quarter Ended March 31, 2017	$ 5.90	$ 3.33
2nd Quarter Ended June 30, 2017	4.89	2.21
3rd Quarter Ended September 30, 2017	3.42	2.00
4th Quarter Ended December 31, 2017	4.49	1.75

(*) OTCQB quotations

On March 9, 2018, the last sales price per share of our common stock was $2.06.

Holders of Record

As of March 9, 2018, there were 424 holders of record of our common stock.

Dividends

There are no restrictions in our articles of incorporation or bylaws that prevent us from declaring dividends. The Nevada Revised Statutes, however, do prohibit us from declaring dividends where after giving effect to the distribution of the dividend:

- We would not be able to pay our debts as they become due in the usual course of business; or
- Our total assets would be less than the sum of our total liabilities plus the amount that would be needed to satisfy the rights of stockholders who have preferential rights superior to those receiving the distribution.

We have never previously declared or paid any cash dividends on our common stock. We currently intend to retain earnings and profits, if any, to support our business strategy and do not intend to pay any cash dividends within the foreseeable future. Any future determination to pay cash dividends will be at the sole discretion of our Board of Directors and will depend upon the financial condition of the Company, our operating results, capital requirements, general business conditions and any other factors that the Board of Directors deems relevant.

Recent Sales of Unregistered Securities

During the three months ended June 30, 2017, we issued 65,000 shares of common stock upon the conversion of 65,000 shares of Series B Preferred Stock. This issuance was made by us pursuant to an exemption from registration provided by Section 3(a)(9) of the Securities Act.

During the three months ended March 31, 2017, we issued 120,000 shares of common stock upon the conversion of 120,000 shares of Series B Preferred Stock. This issuance was made by us pursuant to an exemption from registration provided by Section 3(a)(9) of the Securities Act.

In March 2017, we issued 125,397 shares of the Company's common stock to Pharmsynthez, our controlling stockholder, in connection with the conversion of its $500,000 convertible promissory note and related interest as a result of the Company's public offering in November 2016 and Pharmsynthez subsequently exercising its rights to the shares. This issuance was made by us pursuant to an exemption from registration provided by (i) Section 4(a)(2) of the Securities Act, in that the transactions was between an issuer and sophisticated investor and did not involve any public offering and (ii) Regulation S promulgated under the Securities Act in that offers, sales and issuances were not made to persons in the United States and no directed selling efforts were made in the United States.

Repurchases of Equity Securities of the Issuer

During 2017 and 2016, we did not repurchase any of our outstanding securities.

ITEM 6 – SELECTED FINANCIAL DATA

We are not required to provide the information required by this Item because we are a smaller reporting company.

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

BUSINESS OVERVIEW

During the year ended December 31, 2017, we began conducting a Phase 2 trial for XBIO-101, with the first patient dosed in October 2017, and expect to generate preliminary data from this trial before the end of 2018.

We continue to commit significant resources to our research and development activities and anticipate continuing to do so for the near future. Although we hold a broad patent portfolio, the focus of our internal development efforts is currently limited to research and development of our lead product candidate XBIO-101 due to capital restraints.

In May 2017, we announced that our strategic collaborator, Shire had terminated further development of SHP656, its polysialylated rFVIII drug candidate being developed using our proprietary PolyXen^{TM} technology. We intend to continue to explore the potential for future collaborations with Shire.

In October 2017, we entered into a Right to Sublicense Agreement (the "Sublicense Agreement") with Baxalta Incorporated, Baxalta US Inc., and Baxalta GmbH (collectively, with their affiliates, "Baxalta") wholly-owned subsidiaries of Shire. Pursuant to the Sublicense Agreement, we granted to Baxalta the right to grant a nonexclusive sublicense to certain patents related to our PolyXen^{TM} technology that were previously exclusively licensed to Baxalta pursuant to an agreement between us and Baxalta (the "Licensed Patents") in connection with products relating to the treatment of blood and bleeding disorders (the "Covered Products"). The term of the Sublicense Agreement continues on a country-to-country basis until the expiration of the last-to-expire Licensed Patents or upon certification from Baxalta that it is not receiving compensation for sales of Covered Products in a given country, whichever is later (the "Term"). Pursuant to the Sublicense Agreement, Baxalta paid us a one-time payment of seven million five hundred thousand dollars ($7,500,000) in November 2017 and agreed to pay us a single digit royalty payment based upon net sales of the Covered Products throughout the Term, each of which is conditioned upon the performance of the sublicense contemplated by the Sublicense Agreement.

Critical Accounting Estimates

The preparation of our financial statements in conformity with U.S. generally accepted accounting principles ("U.S. GAAP") requires us to make estimates, judgments and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of revenue, costs and expenses during the reporting period. On an ongoing basis, we evaluate our estimates that are based on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. The result of these evaluations forms the basis for making judgments about the carrying values of assets and liabilities and the reported amount of expenses that are not readily apparent from other sources. Because future events and their effects cannot be determined with certainty, actual results and outcomes could differ materially from our estimates, judgments and assumptions.

Management believes that the following accounting estimates are the most critical to aid in fully understanding and evaluating our reported financial results, and they require management's most difficult subjective or complex judgments, resulting from the need to make estimates about the effect of matters that are inherently uncertain. The following narrative describes these critical accounting estimates, judgments and assumptions and the effect if actual results differ from these assumptions.

Revenue Recognition

We derive our revenue from our supply, license and collaboration arrangements with pharmaceutical and biotechnology partners, some of which include royalty agreements based on potential net sales of approved commercial pharmaceutical products. Revenue from our collaborative partners is generally paid directly by the partners and is recognized on the accrual basis when all the following criteria are met: (i) persuasive evidence of an arrangement exists, (ii) delivery (or passage of title) has occurred or services have been rendered, (iii) the seller's price to the buyer is fixed or determinable, and (iv) collectability is reasonably assured.

The terms of our license agreements include delivery of an IP license to a collaboration partner. We may be compensated under license arrangements through a combination of non-refundable upfront receipts, development and regulatory objective receipts and royalty receipts on future product sales by partners.

Non-refundable upfront license payments and development and regulatory milestone payments received from license and collaboration agreements that include future obligations, such as supply obligations, are recognized ratably over the Company's expected performance period for each respective arrangement. We make our best estimate of the period over which we expect to fulfill our performance obligations, which may include technology transfer assistance, research activities, clinical development activities, and manufacturing activities from development through the commercialization of the product. Given the uncertainties of these collaboration arrangements, significant judgment is required to determine the duration of the performance period. Non-refundable upfront license fees received, whereby our continued performance or future obligations are considered inconsequential or perfunctory to the relevant licensed technology, are recognized as revenue upon delivery of the technology. Reimbursements for research and development services completed by us related to the collaboration agreements are recognized in operations as revenue on a gross basis.

We expect to receive royalty revenue in the period of sale, based on the underlying contract terms, provided that the reported sales are reliably measurable, we have no remaining performance obligations, and all other revenue recognition criteria are met.

Our license and collaboration agreements with certain collaboration partners could also provide for future milestone receipts to us based solely upon the performance of the respective collaboration partner in consideration of deadline extensions or upon the achievement of specified sales volumes of approved drugs. For such receipts, we expect to recognize the receipts as revenue when earned under the applicable contract terms on a performance basis or ratably over the term of the agreement. These receipts may also be recognized as revenue when our continued performance or future obligations are considered inconsequential or perfunctory.

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)* ("ASU 2014-09"), which supersedes existing revenue recognition guidance. The standard's core principle is that a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods and services. The standard defines a five-step process to achieve this principle and will require companies to use more judgment and make more estimates than under the current guidance. The Company expects that these judgments and estimates will include identifying performance obligations in the customer contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. ASU 2014-09 also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts. The Company does not have any revenue generating contracts with customers and, therefore, the adoption of this new revenue standard will not have a material impact on the consolidated financial statements. The Company adopted the new revenue standard on January 1, 2018 using the modified retrospective approach.

Research and Development Expenses

Research and development expenses consist of expenses incurred in performing research and development activities, including compensation and benefits, facilities expenses, overhead expenses, clinical trial and related clinical manufacturing expenses, fees paid to contract research organizations ("CROs") and contract manufacturing organizations and other outside expenses. We expense research and development costs as incurred. We expense upfront, non-refundable payments made for research and development services as obligations are incurred. The value ascribed to intangible assets acquired but which have not met capitalization criteria is expensed as research and development at the time of acquisition.

We are required to estimate accrued research and development expenses at each reporting period. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual costs. The majority of our service providers invoice us in arrears for services performed, on a pre-determined schedule or when contractual milestones are met. However, some require advanced payments. We make estimates of accrued expenses as of each balance sheet date in the financial statements based on facts and circumstances known at that time. We periodically confirm the accuracy of the estimates with the service providers and make adjustments, if necessary. Examples of estimated accrued research and development expenses include fees paid to:

- program managers in connection with overall program management of clinical trials;
- CROs in connection with clinical trials; and
- investigative sites in connection with clinical trials.

We base our expenses related to clinical trials on our estimates of the services received and efforts expended pursuant to quotes and contracts with multiple research institutions and CROs that conduct and manage clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to vendors will exceed the level of services provided and result in a prepayment of the expense. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we adjust the accrual or prepaid accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period. To date, there have not been any material adjustments to our prior estimates of accrued research and development expenses.

Embedded Derivatives Related to Debt Instruments

Embedded derivatives that are required to be bifurcated from their host contract are evaluated and valued separately from the host contract (i.e., the debt instrument). Features of our debt instruments that meet the definition of a derivative and the criteria for separate accounting include the conversion feature and certain put options.

The fair value of each embedded derivative is valued independently using a "with-and-without" method. The "with-and-without" methodology involves valuing the whole instrument on an as-is basis and then valuing the instrument without the individual embedded derivative. The difference between the entire instrument with all of the embedded derivatives compared to the instrument without the individual embedded derivative is the fair value of that individual derivative. The embedded derivatives are settled when the underlying debt instrument is settled. Therefore, there are three possible settlement mechanisms: the debt instrument can be converted into equity, repaid early, or held to maturity.

Embedded derivatives are valued individually and recorded as a compound derivative. The compound derivative is presented together with the host debt instrument and the related debt discount on a combined basis. Changes in the estimated fair value of the bifurcated embedded derivatives are reported as gains and losses in the consolidated statement of comprehensive loss each reporting period.

Share-based Payments

Share-based payments includes grants of options and restricted stock units ("RSUs") to employees and non-employees to purchase shares of common stock, Joint Share Ownership Plan ("JSOP") awards to employees, as well as agreements to issue common stock in exchange for services provided by non-employees.

Shared-based compensation expense is based on the estimated fair value of the option or calculated using the Black-Scholes option pricing model. Determining the appropriate fair value model and related assumptions requires judgment, including estimating share price volatility and expected terms of the awards. The expected volatility rates are estimated based on our actual volatility and of comparable public companies over the expected term of the option. The expected terms represent the time that options are expected to be outstanding. We account for forfeitures as they occur and not at the time of grant. Prior to January 1, 2017, we estimated forfeitures at the time of grant utilizing a 0% rate and revised those estimates in subsequent periods if actual forfeitures differ from those estimates. The Company has not paid dividends and does not anticipate paying cash dividends in the foreseeable future and, accordingly, uses an expected dividend yield of zero. The risk-free interest rate is based on the rate of U.S. Treasury securities with maturities consistent with the estimated expected term of the awards. Upon exercise, stock options are redeemed for newly issued shares of common stock. RSUs are redeemed for newly issued shares of common stock as the vesting provisions of the grant are met.

For employee options that vest based solely on service conditions, the fair value measurement date is generally on the date of grant and the related compensation expense is recognized on a straight-line basis over the requisite vesting period of the awards. For non-employee options, the fair value measurement date is the earlier of the date the performance of services is complete or the date the performance commitment has been reached. We determine that the fair value of the stock options is more reliably measurable than the fair value of the services received. Compensation expense related to stock options granted to non-employees that vest based solely on service conditions is subject to re-measurement at each reporting period until the options vest and is recognized on a straight-line basis over requisite vesting period of the awards.

The fair value of common stock awards issued in exchange for services provided by non-employees is generally determined by using the fair value of the services provided, as this provides the most reliable measure of the fair value of the awards. Share-based payments expense is recognized as services are rendered on a straight-line basis. The assumptions used in calculating the fair value of the common stock awards represent our best estimates and involve inherent uncertainties and the application of our judgment. As a result, if factors change and we use different assumptions, share-based payments expense related to the common stock awards could be materially different in the future.

Warrants

In connection with certain financing, consulting and collaboration arrangements, we issued warrants to purchase shares of our common stock. Outstanding warrants are standalone instruments that are not puttable or mandatorily redeemable by the holder and are classified as equity awards. We measure the fair value of the awards using the Black-Scholes option pricing model, which requires the input of subjective assumptions and judgments, including estimating the expected term of the awards and the share price volatility, at each reporting period until the measurement date is reached. The expected term is deemed to be the contractual life of the warrant and we determine the expected volatility based on a weighted-average of the historical volatility of a peer group of comparable publicly traded companies with drug candidates in similar stages of development to our drug candidates in conjunction with our historical volatility.

All other warrants are recorded at fair value as expense on a straight-line basis over the requisite service period or at the date of issuance, if there is not a service period or if service has already been rendered. For warrants that contain vesting triggers based on the achievement of certain objectives, we apply judgment to estimate the probability and timing of the achievement of those objectives. These estimates involve inherent uncertainties, and as a result, if the probability or timing of the achievement of those objectives change, expense related warrants could be materially different in the future.

Warrants issued to collaboration partners in conjunction with the issuance of common stock are recorded at fair value as a reduction of additional paid-in capital of the common stock issued.

For warrants issued in connection with financing arrangements the Company allocates the proceeds based on the relative fair value of the award and other instrument(s).

Goodwill and Indefinite-lived Intangible Assets

Goodwill

Goodwill is not amortized but is reviewed for impairment annually as of October 1, or when events or changes in the business environment indicate that all, or a portion, of the carrying value of the reporting unit may no longer be recoverable. Under this method, we compare the fair value of our reporting unit to its carrying value. If the fair value is less than the carrying amount, a more detailed analysis is performed to determine if goodwill is impaired. An impairment loss, if any, is measured as the excess of the carrying value of goodwill over the fair value of goodwill. We also have the option to first assess qualitative factors to determine whether the existence of events or circumstances leads us to determine that it is more likely than not (that is, a likelihood of more than 50%) that goodwill is impaired. If we choose to first assess qualitative factors and it is determined that it is not more likely than not goodwill is impaired, we are not required to take further action to test for impairment. We also have the option to bypass the qualitative assessment and perform only the quantitative impairment test, which we may choose to do in some periods but not in others. As the option to perform the qualitative assessment is not a permanent election, we reassess this option during each annual impairment review.

We determine our reporting unit by identifying the components of our operating segment with similar economic characteristics based on quantitative and qualitative factors that have discrete financial information available. We determined that we have one reporting unit as of October 1, 2017 and 2016, the dates of our annual impairment reviews. Based on our annual impairment reviews, we used the quantitative method and determined no adjustment to the carrying value of goodwill would be necessary as the fair value of our reporting unit exceeded its respective carrying value as of October 1, 2017 and 2016, respectively. There can be no assurance that future events will not result in an impairment of goodwill.

Indefinite-lived Intangible Assets

Our indefinite-lived intangible assets consist of acquired in-process research and development ("IPR&D"). IPR&D intangible assets are considered indefinite-lived intangible assets until completion or abandonment of the associated research and development efforts. IPR&D is not amortized but is reviewed for impairment annually as of October 1, or when events or changes in the business environment indicate the carrying value may be impaired. If the fair value of the intangible asset is less than the carrying amount, we perform a quantitative test to determine the fair value. The impairment loss, if any, is measured as the excess of the carrying value of the intangible asset over its fair value. We also have the option to first assess qualitative factors to determine whether the existence of events or circumstances leads us to determine that it is more likely than not (that is, a likelihood of more than 50%) that our indefinite-lived intangible asset is impaired. If we choose to first assess qualitative factors and it is determined that it is not more likely than not our indefinite-lived intangible asset is impaired, we are not required to take further action to test for impairment. We also have the option to bypass the qualitative assessment and perform only the quantitative impairment test, which we may choose to do in some periods but not in others. As the option to perform the qualitative assessment is not a permanent election, we reassess this option during each annual impairment review. During 2017 and 2016, we used the quantitative method and determined the fair value of the indefinite-lived intangible asset exceeded its carrying value as of October 1, 2017 and 2016.

Significant judgments are inherent in the calculation of fair value. With the assistance of an independent third party, we calculated the fair value of our IPR&D by using the Multi-Period Excess-Earnings Method (the "MPEEM") which is a form of the income approach. Under the MPEEM, the fair value of an intangible asset is equal to the present value of the asset's incremental after-tax cash flows (excess earnings) remaining after deducting the market rates of return on the estimated value of contributory assets (contributory charge) over its remaining useful life. This method requires us to make long-term projections of the amount and timing of income and expenses related to development and commercialization of the acquired intangible asset and assumptions regarding the rate of return on contributory assets, the weighted average cost of capital and the discount rate for estimated future after-tax cash flows. Specifically, this method took into account our estimates of future incremental milestone payments that may be achieved upon completion of clinical trial stages, regulatory approval and sales goals upon commercialization, as well as our expected royalty income based on sales upon commercialization. Projected expenses are based on our forecasted spend required to complete the development of our IPR&D, which will require the Company to raise further capital to fund the development. Our projections are estimates subject to change based on several factors including the results of clinical trials and delays in regulatory approval. The discount rate used is commensurate with the uncertainties associated with the economic estimates described above and reflects the stage of development, the time and resources needed to complete the development of the product and the risks of advancement through regulatory approval processes.

Key assumptions utilized in the fair valuation of our indefinite-lived intangible asset are as follows:

- Discount rate – 45.0%
- Estimated aggregate milestone receipts – approximately $300 million
- Royalty rates – 10% of net sales

While we believe reasonable estimates and appropriate assumptions were utilized to calculate the fair value of IPR&D, it is possible a material change could occur. Use of different estimates and judgments could yield materially different results in our analysis and could result in materially different asset values or expense.

There can be no assurance that we will be able to successfully develop and complete the acquired IPR&D program and profitably commercialize the underlying drug candidates before our competitors develop and commercialize similar products, or at all. Moreover, if the acquired IPR&D program fails or is abandoned during development, then we may not realize the value we have estimated and recorded in our financial statements on the acquisition date, and we may also not recover the research and development investment made since the acquisition date to further develop that program. If such circumstances were to occur, our future operating results could be materially adversely impacted.

We did not record an impairment charge as a result of our goodwill or indefinite-lived intangible asset impairment tests in 2017 or 2016. We will continue to closely monitor the performance of our indefinite-lived intangible asset and reporting unit. If the business experiences adverse changes in our key assumptions and judgments, we will perform an interim goodwill and/or indefinite-lived intangible asset impairment analysis. There can be no assurance that future events will not result in an impairment of our goodwill or indefinite-lived intangible asset. As a result of the going concern uncertainty discussed under *Liquidity and Capital Resources* below, the recoverability and classification of the Company's intangible assets and goodwill could be adversely affected.

RESULTS OF OPERATIONS

The table below sets forth the comparison of our historical results of operations for the year ended December 31, 2017 to the year ended December 31, 2016.

Description	2017	2016	Increase (Decrease)	Percentage Change
Revenues:				
Licenses and collaboration services	$ 7,585,000	$ –	$ 7,585,000	100%
Milestones	–	3,000,000	(3,000,000)	(100)%
Operating costs and expenses:				
Cost of research and development revenue	(156,119)	–	156,119	100%
Research and development	(4,060,000)	(43,737,814)	(39,677,814)	(90.7)%
General and administrative	(6,937,643)	(6,692,786)	244,857	3.7%
Loss from operations	$ (3,568,762)	$ (47,430,600)	$ (43,861,838)	(92.5)%
Other income (expense):				
Change in fair value of derivative liability	$ –	$ 2,125,113	$ (2,125,113)	(100.0)%
Loss on issuance of hybrid debt instruments	–	(1,690,784)	(1,690,784)	(100.0)%
Loss on conversion of debt	–	(6,394,921)	(6,394,921)	(100.0)%
Other expense	(41,096)	(85,374)	(44,278)	(51.9)%
Interest income	16,544	32	16,512	51,600.0%
Interest expense	(1,818)	(729,572)	(727,754)	(99.8)%
Net loss	$ (3,595,132)	$ (54,206,106)	$ (50,610,974)	(93.4)%

Revenue

Revenue represents license and collaboration services in 2017 and milestone payments in 2016.

In October 2017, we entered into a Sublicense Agreement with Baxalta. Pursuant to the Sublicense Agreement, Baxalta paid us a one-time payment of seven million five hundred thousand dollars ($7,500,000) in November 2017 and agreed to pay us single digit royalty payments based upon net sales of the Covered Products throughout the Term, each of which is conditioned upon the performance of the sublicense contemplated by the Sublicense Agreement. We recognized revenue of $7.5 million in 2017 related to this payment.

Research and development revenue represents collaboration services related to research and development programs conducted on behalf of third parties in 2017.

We recorded $3.0 million in milestone revenue from Shire for the year ended December 31, 2016 in connection with Shire's initiation of the Phase 1/2 clinical trial of SHP656. Shire terminated further development of SHP656 in 2017.

Cost of Revenue

There was no cost of revenue associated with the sub-license revenue for the year ended December 31, 2017. Cost of research and development revenue represents collaboration services related to research and development programs conducted on behalf of third parties in 2017. There was no cost of revenue for the year ended December 31, 2016.

Research and Development Expense

Overall, corporate R&D expenses for the year ended December 31, 2017 decreased by $39.7 million primarily due to the decrease of IPR&D expense of $39.5 million. During the year ended December 31, 2016, we expensed $39.5 million of IPR&D associated with the closing of our acquisition of XBIO-101 from Kevelt. There was no similar expense in 2017. Excluding the effects of the IPR&D expense, R&D expenses decreased $0.2 million, or 4.2% to $4.1 million from $4.2 million in the comparable period in 2016.

The table below sets forth the research and development expenses incurred by category of expense for the years ended December 31, 2017 and 2016.

Category of Expense	Year ended December 31, 2017	2016
IPR&D expense	$ –	$ 39,500,000
Outside services and Contract Research Organizations	3,094,583	1,845,381
Share-based expense	101,400	1,425,995
Personnel costs	568,376	721,168
Other	295,641	245,270
Total research and development expense	$ 4,060,000	$ 43,737,814

The decrease in R&D expenses exclusive of the IPR&D charge was primarily due to a decrease in share-based expense related to warrants issued to Serum Institute in 2016. In addition, personnel costs for the year ended December 31, 2016 included certain bonus payments to employees that were earned in connection with our November 2016 public offering. No such bonuses were earned in 2017. These decreases were substantially offset by an increase in outside services and CROs as we commenced our Phase 2 clinical trial for XBIO-101.

General and Administrative Expense

General and administrative expenses increased by approximately $0.2 million or 3.7% for the year ended December 31, 2017 to $6.9 million from $6.7 million in the comparable period in 2016. The most significant drivers of the change were related to increases in personnel costs including an increase in salary, share-based compensation and travel as well as an approximate $0.6 million accrual recorded in the fourth quarter of 2017 in connection with severance to be paid out in 2018. In December 2016, we hired our Chief Operating Officer and, in April 2017, we hired our Chief Financial Officer. Substantially all of the accrued severance related to a settlement agreement with our former Chief Executive Officer who separated from the Company in November 2017. These increases were substantially offset by a decrease in costs associated with our public offering in 2016 and a decrease in consulting costs as a result of the hiring of our full-time Chief Financial Officer.

Hybrid Debt Instruments

During the year ended December 31, 2016, we recorded a net loss of approximately $0.3 million associated with hybrid debt instruments representing a $1.7 million loss on issuance and $0.7 million of interest and amortization expenses associated with the instruments, both offset by a $2.1 million gain from changes in derivative fair value. The gain recognized primarily related to the final mark-to-market immediately prior to conversion of the host debt instruments. An aggregate of approximately $6.4 million in loss was recognized on the conversion of debt in April and November 2016. The conversion rate was $4.95 per share. As such, we issued to Pharmsynthez approximately 1.4 million shares of common stock in connection with conversion of the convertible notes. The related embedded derivatives, which had been bifurcated from the host debt and accounted for separately, were settled by action of the conversion. All hybrid debt instruments were settled in November 2016 and none were issued in 2017 or outstanding as of December 31, 2017 and 2016, respectively.

Other Expense

Other expense decreased approximately $44,000, or 51.9%, to approximately $41,000 for the year ended December 31, 2017 from approximately $85,000 in 2016. This decrease was primarily related to changes in foreign currency exchange rates between periods.

Interest Expense

Interest expense decreased by approximately $0.7 million, or 99.8%, to approximately $2,000 for the year ended December 31, 2017. The decrease is due to the settlement of all outstanding debt in connection with the proceeds from our underwritten public offering in November 2016.

Liquidity and Capital Resources

We incurred a net loss of approximately $3.6 million for the year ended December 31, 2017. We had an accumulated deficit of approximately $145.9 million at December 31, 2017 as compared to an accumulated deficit of approximately $142.3 million as of December 31, 2016. Working capital was approximately $3.9 million and $6.5 million at December 31, 2017 and December 31, 2016, respectively. During the year ended December 31, 2017, our working capital decreased by $2.6 million due primarily to outflows for general operating costs and costs related to our XBIO-101 phase 2 clinical trial. We expect to continue incurring losses for the foreseeable future and will need to raise additional capital or pursue other strategic alternatives in the near term in order to continue the pursuit of our business plan and continue as a going concern.

Our principal source of liquidity consists of cash. At December 31, 2017, we had approximately $5.5 million in cash and $1.9 million in accounts payable and accrued expenses. At December 31, 2016, we had approximately $4.0 million in cash and $1.8 million in accounts payable and accrued expenses.

We have historically relied upon sales of our equity securities to fund our operations. Since 2005, we have raised approximately $60.0 million in proceeds from offerings of our common and preferred stock, including net proceeds of approximately $9.0 million from our underwritten public offering in November 2016. We have also received approximately $20.0 million from revenue producing activities from 2005 through December 31, 2017, including a cash payment from Shire of a $3.0 million clinical milestone payment in January 2017 and a cash payment from Baxalta of a $7.5 million sublicense payment in November 2017. More than 90% of the milestone and sublicense revenue received to date has been from a single collaborator, Shire. We expect the majority of our funding through equity or equity-linked instruments, debt financings and/or licensing agreements to continue as a trend for the foreseeable future.

In October 2017, we entered into a Sublicense Agreement with Baxalta. Pursuant to the Sublicense Agreement, we granted to Baxalta the right to grant a nonexclusive sublicense to certain patents related to our PolyXen technology that were previously exclusively licensed to Baxalta in connection with the Covered Products. Pursuant to the Sublicense Agreement, Baxalta paid us a one-time payment of seven million five hundred thousand dollars ($7,500,000) in November 2017 and agreed to pay us single digit royalty payments based upon net sales of the Covered Products throughout the terms of the Sublicense Agreement, each of which is conditioned upon the performance of the sublicense contemplated by the Sublicense Agreement.

We estimate that our existing resources will only be able to fund our planned operations, existing obligations and contractual commitments through the second quarter of 2018. This projection is based on our current expectations regarding projected staffing expenses, working capital requirements, capital expenditure plans and anticipated revenues. Given our current working capital constraints, we have attempted to minimize cash commitments and expenditures for external research and development and general and administrative services to the greatest extent practicable. We will need to raise additional working capital in the near term in order to fund our future operations.

We have no committed sources of additional capital. Our management believes that we have access to capital resources through possible public or private equity offerings, debt financings, corporate collaborations, related party funding or other means; however, we have not secured any commitment for additional financing at this time. The terms, timing and extent of any future financing will depend upon several factors including the achievement of progress in our clinical development programs, our ability to identify and enter into licensing or other strategic arrangements and factors related to financial, economic and market conditions, many of which are beyond our control.

Our management evaluates whether there are conditions or events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern within one year after the date that the financial statements are issued. We have incurred substantial losses since our inception and we expect to continue to incur operating losses in the near-term. These factors raise substantial doubt about our ability to continue as a going concern. As a result, our independent registered public accounting firm included an explanatory paragraph in its report on our audited financial statements for the year ended December 31, 2017 expressing doubt as to our ability to continue as a going concern. We will need to raise additional capital in order to sustain our operations. If we are unable to secure additional funds on a timely basis or on acceptable terms, we may be required to defer, reduce or eliminate significant planned expenditures, restructure, curtail or eliminate some or all of our development programs or other operations, reduce general and administrative expenses, and delay or cease the purchase of clinical research services, dispose of technology or assets, pursue an acquisition of our company by another party at a price that may result in a loss on investment for our stockholders, enter into arrangements that may require us to relinquish rights to certain of our drug candidates, technologies or potential markets, file for bankruptcy or cease operations altogether.

We continue to seek appropriate out-license arrangements for our PolyXen™ and ErepoXen™ technologies, among others, but are currently unable to reliably predict whether or when we may enter into an agreement. Due to the uncertainties inherent in the clinical research process and unknown future market conditions, there can be no assurance any of our technologies will lead to any future income.

Cash Flows from Operating Activities

Cash flows provided by operating activities for the year ended December 31, 2017 totaled approximately $1.5 million primarily due to the receipt of the $3.0 million clinical milestone payment from Shire in January 2017. Cash flow from this clinical milestone payment was substantially offset by our net loss of $3.6 million, which included $1.8 million of non-cash share-based compensation expense.

Cash flows used in operating activities for the year ended December 31, 2016 totaled approximately $8.8 million. The $8.8 million includes net operating cash uses of approximately $4.3 million in consulting, legal and other professional service fees, approximately $2.3 million in personnel costs, including scientific staff, approximately $1.2 million in program-specific clinical development costs, and approximately $0.9 million in insurance, office, travel, technology and regulatory and statutory costs.

Cash Flows from Investing Activities

Cash flows used in investing activities for the year ended December 31, 2017 included approximately $9,000 for the purchase of assets consisting primarily of computer equipment.

Cash flows used in investing activities for the year ended December 31, 2016 included approximately $17,000 for the purchase of assets consisting of laboratory and computer equipment.

As of December 31, 2017, there were no material commitments for capital expenditures.

Cash Flow from Financing Activities

For the year ended December 31, 2017, there were no significant cash sources or uses from financing activities.

For the year ended December 31, 2016, we raised approximately $4.5 million and approximately $9.0 million from the issuances of short-term promissory notes and the public offering, respectively. From the proceeds of the public offering, we repaid approximately $0.8 million of debt liabilities in cash and settled the remaining in non-cash conversion transactions.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements that have or are reasonably likely to have a current or future material effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

Contractual Obligations

Contractual obligations represent future cash commitments and liabilities under agreements with third parties, and exclude contingent liabilities for which we cannot reasonably predict future payment. Our contractual obligations result from property leases for office space. Although we do have obligations for CRO services, the table below excludes potential payments we may be required to make under our agreements with CROs because timing of payments and actual amounts paid under those agreements may be different depending on the timing of receipt of goods or services or changes to agreed-upon terms or amounts for some obligations, and those agreements are cancelable upon written notice by the Company and therefore, not long-term liabilities. The contracts also contain variable costs that are hard to predict as they are based on such things as patients enrolled and clinical trial sites, which can vary and, therefore, are also not included in the table below. Additionally, the expected timing of payment of the obligations presented below is estimated based on current information.

The following table represents our contractual obligations as of December 31, 2017, aggregated by type:

	Payments Due by Period				
	Total	Less than 1 year	1 – 3 years	3 – 5 years	More than 5 years
Operating lease obligations	$ 148,246	$ 123,663	$ 24,583	$ –	$ –
Total	$ 148,246	$ 123,663	$ 24,583	$ –	$ –

Recent Accounting Standards

Refer to Note 2, *Summary of Significant Accounting Policies*, of the accompanying financial statements in Item 8 herein.

ITEM 7A – QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are not required to provide the information required by this Item because we are a smaller reporting company.

Item 8 FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of
Xenetic Biosciences, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Xenetic Biosciences, Inc. (the "Company") as of December 31, 2017 and 2016, and the related consolidated statements of comprehensive loss, stockholder's equity and cash flows for each of the two years in the period ended December 31, 2017 and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2017 and 2016, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2017, in conformity with accounting principles generally accepted in the United States of America.

Explanatory Paragraph/Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 1 to the financial statements, the Company has had recurring net losses and continues to experience negative cash flows from operations. These conditions raise substantial doubt about its ability to continue as a going concern. Management's plans regarding those matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

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

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

/s/ Marcum llp

Marcum llp

We have served as the Company's auditor since 2015.

Boston, Massachusetts
March 30, 2018

XENETIC BIOSCIENCES, INC.
CONSOLIDATED BALANCE SHEETS

	December 31, 2017	December 31, 2016
ASSETS		
Current assets:		
Cash	$ 5,533,062	$ 4,048,131
Restricted cash	66,510	66,510
Accounts receivable	–	3,000,000
Prepaid expenses and other	285,005	1,224,009
Total current assets	5,884,577	8,338,650
Property and equipment, net	27,846	42,366
Goodwill	3,283,379	3,283,379
Indefinite-lived intangible assets	9,243,128	9,243,128
Other assets	724,713	66,342
Total assets	$ 19,163,643	$ 20,973,865
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 786,779	$ 1,006,903
Accrued expenses	1,135,653	838,888
Other current liabilities	21,234	20,205
Total current liabilities	1,943,666	1,865,996
Deferred tax liability	2,918,518	2,918,518
Other liabilities	–	19,876
Total liabilities	4,862,184	4,804,390
Commitments and contingent liabilities (Note 14)		
Stockholders' equity:		
Preferred stock, 10,000,000 shares authorized		
Series B, $0.001 par value: 2,120,742 and 2,305,742 issued and outstanding as of December 31, 2017 and December 31, 2016, respectively	2,120	2,305
Series A, $0.001 par value: 970,000 shares issued and outstanding as of December 31, 2017 and December 31, 2016	970	970
Common stock, $0.001 par value; 45,454,546 shares authorized as of December 31, 2017 and December 31, 2016; 9,041,426 and 8,731,029 shares issued as of December 31, 2017 and December 31, 2016, respectively; 8,717,541 and 8,407,144 shares outstanding as of December 31, 2017 and December 31, 2016, respectively	9,040	8,730
Additional paid in capital	165,249,912	163,522,921
Accumulated deficit	(145,933,137)	(142,338,005)
Accumulated other comprehensive income	253,734	253,734
Treasury stock	(5,281,180)	(5,281,180)
Total stockholders' equity	14,301,459	16,169,475
Total liabilities and stockholders' equity	$ 19,163,643	$ 20,973,865

The accompanying notes are an integral part of these consolidated financial statements.

XENETIC BIOSCIENCES, INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

	YEAR ENDED DECEMBER 31,	
	2017	**2016**
Revenue		
Licenses	$ 7,500,000	$ –
Milestones	–	3,000,000
Collaboration services	85,000	–
Total revenues	7,585,000	3,000,000
Operating costs and expenses:		
Cost of research and development revenue	(156,119)	–
Research and development	(4,060,000)	(43,737,814)
General and administrative	(6,937,643)	(6,692,786)
Loss from operations	(3,568,762)	(47,430,600)
Other income (expense):		
Change in fair value of derivative liability	–	2,125,113
Loss on issuance of hybrid debt instruments	–	(1,690,784)
Loss on conversion of debt	–	(6,394,921)
Other expense	(41,096)	(85,374)
Interest income	16,544	32
Interest expense	(1,818)	(729,572)
Total other expense	(26,370)	(6,775,506)
Net loss	(3,595,132)	(54,206,106)
Accretion of beneficial conversion feature on convertible preferred stock	–	(4,035,260)
Net loss applicable to common stockholders	(3,595,132)	(58,241,366)
Total comprehensive loss	$ (3,595,132)	$ (54,206,106)
Basic and diluted loss per share applicable to common stockholders	$ (0.41)	$ (7.84)
Weighted-average shares of common stock outstanding, basic and diluted	8,665,763	7,430,574

The accompanying notes are an integral part of these consolidated financial statements.

XENETIC BIOSCIENCES, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

	Preferred Stock		Common Stock						
	Number of Shares	Par Value ($0.001)	Number of Shares	Par Value ($0.001)	Additional Paid in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Treasury Stock	Total Stockholders' Equity
Balance as of January 1, 2016	–	$ –	4,909,686	$ 4,909	$ 99,763,101	$ (88,131,899)	$ 253,734	$(5,281,180)	$ 6,608,665
Issuance of common stock to vendors	–	–	253,630	254	1,174,383	–	–	–	1,174,637
Exchange of common stock for Series A preferred stock	970,000	970	(970,000)	(970)	–	–	–	–	–
Warrant expense	–	–	–	–	1,121,466	–	–	–	1,121,466
Issuance of warrants in connection with debt (net of issuance costs of $38,163)	–	–	–	–	2,069,673	–	–	–	2,069,673
Conversion of notes	–	–	1,313,132	1,313	12,014,887	–	–	–	12,016,200
Settlement of accrued interest in common stock	–	–	59,904	60	237,184	–	–	–	237,244
Issuance of common stock in connection with completion of asset acquisition	–	–	3,045,455	3,045	34,899,399	–	–	–	34,902,444
Issuance of warrants in connection with completion of asset acquisition	–	–	–	–	853,039	–	–	–	853,039
Issuance of Series B preferred stock in public offering (net of issuance costs of $319,343)	2,424,242	2,424	–	–	5,703,577	–	–	–	5,706,001
Issuance of Warrants in public offering (net of issuance costs of $210,657)	–	–	–	–	3,763,997	–	–	–	3,763,997
Record beneficial conversion feature in connection with public offering	–	–	–	–	4,035,260	–	–	–	4,035,260
Acrete beneficial conversion feature in connection with public offering	–	–	–	–	(4,035,260)	–	–	–	(4,035,260)
Conversion of Series B preferred stock to shares of common stock	(118,500)	(119)	118,500	119	–	–	–	–	–
Share-based payments	–	–	–	–	1,922,215	–	–	–	1,922,215
Adjust shares in connection with 2014 reverse merger and 2016 reverse split	–	–	722	–	–	–	–	–	–
Net loss	–	–	–	–	–	(54,206,106)	–	–	(54,206,106)
Balance as of December 31, 2016	3,275,742	$ 3,275	8,731,029	$ 8,730	$163,522,921	$(142,338,005)	$ 253,734	$(5,281,180)	$ 16,169,475
Conversion of notes	–	–	125,397	125	(125)	–	–	–	–
Conversion of Series B preferred stock to shares of common stock	(185,000)	(185)	185,000	185	–	–	–	–	–
Share-based payments	–	–	–	–	1,784,129	–	–	–	1,784,129
Common stock awards to vendors	–	–	–	–	69,303	–	–	–	69,303
Warrant expense	–	–	–	–	(126,316)	–	–	–	(126,316)
Net loss	–	–	–	–	–	(3,595,132)	–	–	(3,595,132)
Balance as of December 31, 2017	3,090,742	$ 3,090	9,041,426	$ 9,040	$165,249,912	$(145,933,137)	$ 253,734	$(5,281,180)	$ 14,301,459

The accompanying notes are an integral part of these consolidated financial statements.

XENETIC BIOSCIENCES, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	YEAR ENDED DECEMBER 31,	
	2017	**2016**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (3,595,132)	$ (54,206,106)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
In-process research and development expense	–	39,500,000
Depreciation	23,784	36,449
Amortization of hybrid debt instrument discount	–	544,480
Non-cash interest expense	–	174,519
Share-based payments	1,784,129	1,922,215
Change in value of warrants issued for services	(126,316)	1,121,466
Vendor share-based payments	135,280	180,971
Change in fair value of derivative liability	–	(2,125,113)
Loss on issuance of hybrid debt instruments	–	1,690,784
Hybrid debt instrument issuance costs	–	(12,093)
Loss on conversion of debt	–	6,394,921
Settlement of accounts payable with common stock	–	243,667
Changes in operating assets and liabilities:		
Accounts receivable	3,000,000	(3,000,000)
Prepaid expenses and other assets	280,633	(234,924)
Accounts payable, accrued expenses and other liabilities	(8,183)	(1,018,411)
Net cash provided by (used in) operating activities	1,494,195	(8,787,175)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	(9,264)	(16,793)
Net cash used in investing activities	(9,264)	(16,793)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of debt	–	4,500,000
Payments on debt	–	(369,958)
Proceeds from issuance of units in offering	–	8,969,998
Payments on loan from related party	–	(380,170)
Net cash provided by financing activities	–	12,719,870
Net change in cash, excluding restricted cash	1,484,931	3,915,902
Cash at beginning of period	4,048,131	132,229
Cash at end of period	$ 5,533,062	$ 4,048,131
SUPPLEMENTAL CASH FLOW INFORMATION:		
Cash paid for interest	$ 1,932	$ 15,836
SUPPLEMENTAL SCHEDULE OF NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Interest paid in common stock	$ –	$ 255,607
Purchase of XBIO-101 IPR&D with common stock	$ –	$ 39,500,000
Issuance of note in settlement of deferred payroll costs	$ –	$ 369,958
Reclassification of related party loan principal to accounts payable	$ –	$ 14,830
Exchange of common stock for Series A preferred stock	$ –	$ 970
Conversion of Series B preferred stock to common stock	$ 185	$ 119
Convertible debt paid in common stock	$ –	$ 7,000,000
Convertible debt paid in public offering units	$ –	$ 500,000
Issuance of warrants in connection with debt	$ –	$ 2,107,836
Recording of derivative liability in connection with debt	$ –	$ 4,120,359
Reclassification of common shares issuable to accounts payable	$ 65,977	$ –
Issuance of common stock for promissory note converted in 2016	$ 125	$ –

The accompanying notes are an integral part of these consolidated financial statements.

1. The Company

Background

Xenetic Biosciences, Inc. ("Xenetic," the "Company," "we" or "us"), incorporated in the state of Nevada and based in Lexington, Massachusetts, is a biopharmaceutical company focused on the discovery, research and development of next-generation biologic drugs and novel oncology therapeutics. The Company's 170+ patent portfolio covers next generation biologic drugs and novel oncology drug therapeutics and provides protection for its current drug candidates and positions it well for strategic partnership and commercialization opportunities. The Company's objective is to leverage its portfolio to maximize opportunities to out-license assets from its portfolio in order to generate working capital to both build long-term stockholder value and provide the Company with the funding necessary for clinical development of its oncology drug candidates through to market launch.

Xenetic incorporates its patented and proprietary technologies into a number of drug candidates currently under development either in-house or with biotechnology and pharmaceutical industry collaborators to create what the Company believes will be the next-generation biologic drugs with improved pharmacological properties over existing therapeutics. While the Company primarily focuses on researching and developing oncology drugs, it also has significant interests in drugs being developed by its collaborators to treat other conditions.

Xenetic's lead investigational drug candidate is oncology therapeutic XBIO-101 (sodium cridanimod) for the treatment of progestin – resistant endometrial cancer. The Company has exclusive rights to develop and commercialize XBIO-101 worldwide, except for specified countries in the Commonwealth of Independent States ("CIS"). XBIO-101 has been granted orphan drug designation by the U.S. Food and Drug Administration ("FDA") for the potential treatment of progesterone receptor negative ("PrR-") endometrial cancer in conjunction with progesterone therapy. The Company is currently conducting a Phase 2 trial for XBIO-101, with the first patient dosed in October 2017, and expects to generate preliminary data from this trial before the end of 2018.

Xenetic's lead proprietary technology is PolyXen™, an enabling platform technology which can be applied to protein or peptide therapeutics. It uses the natural polymer polysialic acid ("PSA") to prolong a drug's circulating half-life and potentially improve other pharmacological properties. PolyXen has been demonstrated in human clinical trials to confer prolonged half-life on biotherapeutics such as recombinant human erythropoietin ("rhEPO") and recombinant Factor VIII ("rFVIII"). The Company believes this technology may be applied to a variety of drug candidates to enhance the properties of the therapeutic, potentially providing advantages over competing products.

In May 2017, Xenetic announced that its strategic collaborator, Shire plc ("Shire"), had terminated further development of SHP656, its polysialylated rFVIII drug candidate being developed using the Company's proprietary PolyXen technology. While Shire's Phase 1/2 trial demonstrated SHP656's efficacy and pharmacokinetic data commensurate with the profile of an extended half-life rFVIII product, the pre-defined once-weekly dosing criterion set forth in the research, development, license and supply agreement was not met. To the Company's knowledge, there were no drug-related adverse events, serious adverse events, or rFVIII inhibitors reported to date. Though the trial's pre-defined once-weekly dosing criterion was not met, the Company intends to continue to explore the potential for future collaborations with Shire.

In October 2017, Xenetic entered into a Right to Sublicense Agreement (the "Sublicense Agreement") with Baxalta Incorporated, Baxalta US Inc., and Baxalta GmbH (collectively, with their affiliates, "Baxalta") wholly-owned subsidiaries of Shire. Pursuant to the Sublicense Agreement, the Company granted to Baxalta the right to grant a nonexclusive sublicense to certain patents related to the Company's PolyXen technology that were previously exclusively licensed to Baxalta pursuant to an agreement between the Company and Baxalta (the "Licensed Patents") in connection with products relating to the treatment of blood and bleeding disorders (the "Covered Products"). The term of the Sublicense Agreement continues on a country-to-country basis until the expiration of the last-to-expire Licensed Patents or upon certification from Baxalta that it is not receiving compensation for sales of Covered Products in a given country, whichever is later (the "Term").

Pursuant to the Sublicense Agreement, Baxalta (i) paid Xenetic a one-time payment of seven million five hundred thousand dollars ($7,500,000) in November 2017 and (ii) agreed to pay the Company a single digit royalty payments based upon net sales of the Covered Products throughout the Term, each of which is conditioned upon the performance of the sublicense contemplated by the Sublicense Agreement.

Xenetic's drug candidates have resulted from its research activities or those of its collaborators and are in the development stage. As a result, the Company commits significant resources to its research and development activities and anticipates continuing to do so for the near future. To date, none of the Company's drug candidates have received regulatory marketing authorization in the U.S. by the FDA nor in any other territories by any applicable agencies. Although the Company holds a broad patent portfolio, the focus of its internal development efforts is currently limited to research and development of its lead product candidate XBIO-101 due to capital restraints.

The Company, directly or indirectly, through its wholly-owned subsidiary, Xenetic Biosciences (U.K.) Limited ("Xenetic UK"), and its wholly-owned subsidiaries, Lipoxen Technologies Limited ("Lipoxen"), Xenetic Bioscience, Incorporated and SymbioTec, GmbH ("SymbioTec"), own various U.S. federal trademark registrations and applications, and unregistered trademarks and service marks, including but not limited to Virexxa®, OncoHist™, PolyXen™, ErepoXen™, ImuXen™, and PulmoXen™.

Going Concern and Management's Plan

The Company incurred a net loss of approximately $3.6 million for the year ended December 31, 2017 and had an accumulated deficit of approximately $145.9 million as of December 31, 2017. The Company had working capital of approximately $3.9 million at December 31, 2017 compared to working capital of approximately $6.5 million at December 31, 2016. The Company expects to continue incurring losses for the foreseeable future and will need to raise additional capital or pursue other strategic alternatives in the near term in order to pursue its business plan and continue as a going concern.

The Company believes that it has access to capital resources through possible public or private equity offerings, debt financings, corporate collaborations or other means; however, it has not secured any commitment for additional financing at this time. The terms, timing and extent of any future financing will depend upon several factors, including the achievement of progress in its clinical development programs, its ability to identify and enter into licensing or other strategic arrangements, and factors related to financial, economic and market conditions, many of which are beyond its control.

While these consolidated financial statements have been prepared on a going concern basis, if the Company does not successfully raise additional working capital, there can be no assurance that the Company will be able to continue its operations and these conditions raise substantial doubt about its ability to continue as a going concern. Under such circumstances, the Company would have to further reduce the planned scale of, or possibly suspend, some or all of its pre-clinical development initiatives and clinical trials. In addition, the Company would have to continue to reduce its general and administrative and other operating expenses and delay or cease the purchase of clinical research services if and until the Company is able to obtain additional financing. The accompanying consolidated financial statements do not include any adjustments related to the recoverability or classification of asset carrying amounts or the amounts and classification of liabilities that may result should the Company be unable to continue as a going concern.

2. Summary of Significant Accounting Policies

Preparation of Financial Statements

These consolidated financial statements have been prepared on the assumption that the Company will be able to realize its assets and discharge its liabilities in the normal course of business. This assumption is presently uncertain and contingent upon the Company's ability to raise additional working capital. The financial statements do not include any adjustments relating to recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

Principles of Consolidation

The consolidated financial statements of the Company include the accounts of Xenetic UK and its wholly owned subsidiaries: Lipoxen, Xenetic Bioscience, Incorporated, and SymbioTec. All material intercompany balances and transactions have been eliminated in consolidation.

Use of Estimates

The consolidated financial statements and accompanying notes are prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP"). The preparation of the financial statements in accordance with U.S. GAAP requires management to make estimates, judgments and assumptions that affect the reported amounts of assets and liabilities, the reported amounts of revenue, costs and expenses in the financial statements and disclosures in the accompanying notes. Actual results and outcomes may differ materially from management's estimates, judgments and assumptions.

Functional Currency Change

Effective April 1, 2015, the functional currency of the Company's foreign subsidiaries changed from the British Pound Sterling to the United States ("U.S.") dollar. The change in functional currency was applied on a prospective basis. Therefore, any gains and losses that were previously recorded in accumulated other comprehensive income remain unchanged.

Foreign Currency Transactions

Realized and unrealized gains and losses resulting from foreign currency transactions arising from exchange rate fluctuations on balances denominated in currencies other than the functional currencies are recognized in "Other income (expense)" in the consolidated statements of comprehensive loss. Monetary assets and liabilities that are denominated in a currency other than the functional currency are re-measured to the functional currency using the exchange rate at the balance sheet date and gains or losses are recorded in the consolidated statements of comprehensive loss.

Fair Value of Financial Instruments

The Company applies the following fair value hierarchy, which prioritizes the inputs used to measure fair value into three levels and bases the categorization within the hierarchy upon the lowest level of input that is available and significant to the fair value measurement. Level 1 inputs are quoted prices in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date. Level 2 utilizes quoted market prices in markets that are not active, broker or dealer quotations, or alternative pricing sources with reasonable levels of price transparency. Level 3 inputs are unobservable inputs for the asset or liability in which there is little, if any, market activity for the asset or liability at the measurement date. See Note 9, *Fair Value Measurements*, for discussion of the Company's fair value measurements.

Cash and Cash Equivalents

The Company considers all highly liquid investments with maturities of 90 days or less from the date of purchase to be cash equivalents. Investments with original maturities of greater than 90 days from the date of purchase but less than one year from the balance sheet date are classified as short-term investments, while investments with maturities of one year or beyond from the balance sheet date are classified as long-term investments. Management determines the appropriate classification of its cash equivalents and investment securities at the time of purchase and re-evaluates such determination as of each balance sheet date.

Restricted Cash

As of December 31, 2017 and 2016, restricted cash represents a certificate of deposit that matures annually, and secures the Company's outstanding letter of credit of approximately $0.1 million for the operating lease in Lexington, Massachusetts. The letter of credit is required to be maintained through the term of the lease, which expires in January 2019.

Concentration of Credit Risk

Financial instruments that subject the Company to concentrations of credit risk include cash and cash equivalents. The Company maintains cash and cash equivalents with various major financial institutions. The Company performs periodic evaluations of the relative credit standing of these financial institutions and limits the amount of credit exposure with any one institution.

Property and Equipment

The Company records property and equipment at cost less accumulated depreciation. Expenditures for major renewals and improvements which extend the life or usefulness of the asset are capitalized. Items of an ordinary repair or maintenance nature are charged directly to operating expense as incurred. The Company calculates depreciation using the straight-line method over the estimated useful lives of the assets:

Asset Classification	Estimated Useful Life
Laboratory equipment	3 years
Office and computer equipment	3 years
Leasehold improvements	5 years or the remaining term of the lease, if shorter
Furniture and fixtures	5 years

The Company eliminates the cost of assets retired or otherwise disposed of, along with the corresponding accumulated depreciation, from the related accounts, and the resulting gain or loss is reflected in the results of operations.

Indefinite-Lived Intangible Assets

Acquired indefinite-lived intangible assets consist of in-process research and development ("IPR&D") related to the Company's business combination with SymbioTec, which was recorded at fair value on the acquisition date. IPR&D intangible assets are considered indefinite-lived intangible assets until completion or abandonment of the associated research and development efforts. Substantial additional research and development may be required before the Company's IPR&D reaches technological feasibility. Upon completion of the IPR&D project, the IPR&D assets will be amortized over their estimated useful lives.

The Company assesses intangible assets with indefinite lives for impairment at least annually as of October 1, or when events or changes in the business environment indicate the carrying value may be impaired. The Company also has the option to first assess qualitative factors to determine whether the existence of events or circumstances leads the Company to determine that it is more likely than not (that is, a likelihood of more than 50%) that the acquired IPR&D is impaired. If the Company chooses to first assess the qualitative factors and it is determined that it is not more likely than not acquired IPR&D is impaired, the Company is not required to take further action to test for impairment. The Company also has the option to bypass the qualitative assessment and perform only the quantitative impairment test, which the Company may choose to perform in some periods but not in others.

No impairment was recorded during the years ended December 31, 2017 and 2016.

Goodwill

Goodwill is comprised of the purchase price of business combinations in excess of the fair value assigned at acquisition to the net tangible and identifiable intangible assets acquired. Goodwill is not amortized. The Company assesses goodwill for impairment at least annually, or when events or changes in the business environment indicate the carrying value may not be fully recoverable. The Company also has the option to first assess qualitative factors to determine whether the existence of events or circumstances leads the Company to determine that it is more likely than not (that is, a likelihood of more than 50%) that goodwill is impaired. If the Company chooses to first assess qualitative factors and it is determined that it is not more likely than not goodwill is impaired, the Company is not required to take further action to test for impairment. The Company also has the option to bypass the qualitative assessment and perform only the quantitative impairment test, which the Company may choose to do in some periods but not in others. The Company performs its annual impairment review as of October 1.

No impairment was recorded during the years ended December 31, 2017 and 2016.

Impairment of Long-Lived Assets

The Company reviews long-lived assets to be held and used, including property and equipment, for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets or asset group may not be fully recoverable. No such impairments were recorded during the years ended December 31, 2017 and 2016.

Evaluation of recoverability is based on an estimate of undiscounted future cash flows resulting from the use of the asset or asset group and its eventual disposition. Impairment, if any, is calculated as the amount by which an asset's carrying value exceeds its fair value, typically using discounted cash flows to determine fair value.

Embedded Derivatives Related to Debt Instruments

Embedded derivatives that are required to be bifurcated from their host contract are evaluated and valued separately from the host contract (i.e., the debt instrument). Features of the Company's debt instrument that meet the definition of a derivative and the criteria for separate accounting include the conversion feature and certain put options.

The fair value of each embedded derivative is valued independently using a "with-and-without" method. The "with-and-without" methodology involves valuing the whole instrument on an as-is basis and then valuing the instrument without the individual embedded derivative. The difference between the entire instrument with all of the embedded derivatives compared to the instrument without the individual embedded derivative is the fair value of that individual derivative. The embedded derivatives are settled when the underlying debt instrument is settled. Therefore, there are three possible settlement mechanisms: the debt instrument can be converted into equity, repaid early, or held to maturity.

Embedded derivatives are valued individually and recorded as a compound derivative. The compound derivative is presented together with the host debt instrument and the related debt discount on a combined basis. Changes in the estimated fair value of the bifurcated embedded derivatives are reported as gains and losses in the consolidated statement of comprehensive loss each reporting period.

Revenue Recognition

The Company enters into supply, license and collaboration arrangements with pharmaceutical and biotechnology partners, some of which include royalty agreements based on potential net sales of approved commercial pharmaceutical products. The Company recognizes revenue when all of the following criteria are met: (i) persuasive evidence of an arrangement exists, (ii) delivery (or passage of title) has occurred or services have been rendered, (iii) the seller's price to the buyer is fixed or determinable, and (iv) collectability is reasonably assured.

The terms of the Company's license agreements include delivery of an IP license to a collaboration partner. The Company may be compensated under license arrangements through a combination of non-refundable upfront receipts, development and regulatory objective receipts and royalty receipts on future product sales by partners. Non-refundable upfront license payments and development and regulatory milestone payments received by the Company in license and collaboration arrangements that include future obligations, such as supply obligations, are recognized ratably over the Company's expected performance period under each respective arrangement. The Company makes its best estimate of the period over which the Company expects to fulfil the Company's performance obligations, which may include technology transfer assistance, research activities, clinical development activities, and manufacturing activities from development through the commercialization of the product. Given the uncertainties of these collaboration arrangements, significant judgment is required to determine the duration of the performance period.

When we enter into an arrangement to sub-license some of our patents we consider the performance obligations to determine if there is a single element or multiple elements to the arrangement as we determine the proper method and timing of revenue recognition. We consider the terms of the license for such elements as price adjustments or refund clauses in addition to any performance obligations for us to provide such as services, patent defense costs, technology support, marketing or sales assistance or any other elements to the arrangement that could constitute an additional deliverable to us that could change the timing of the revenue recognition. Non-refundable upfront license fees received, whereby continued performance or future obligations are considered inconsequential or perfunctory to the relevant licensed technology, are recognized as revenue upon delivery of the technology.

The Company expects to recognize royalty revenue in the period of sale, based on the underlying contract terms, provided that the reported sales are reliably measurable, the Company has no remaining performance obligations, and all other revenue recognition criteria are met.

Reimbursements for research and development services completed by the Company related to the collaboration agreements are recognized in operations as revenue on a gross basis.

The Company's license and collaboration agreements with certain collaboration partners could also provide for future milestone receipts to the Company based solely upon the performance of the respective collaboration partner in consideration of deadline extensions or upon the achievement of specified sales volumes of approved drugs. For such receipts, the Company expects to recognize the receipts as revenue when earned under the applicable contract terms on a performance basis or ratably over the term of the agreement. These receipts may also be recognized as revenue when continued performance or future obligations by the Company are considered inconsequential or perfunctory.

See also Note 4, *Significant Strategic Drug Development Collaborations – Related Parties*.

Research and Development Expenses

Research and development expenses consist of expenses incurred in performing research and development activities, including compensation and benefits, facilities expenses, overhead expenses, clinical trial and related clinical manufacturing expenses, fees paid to contract research organizations ("CROs") and contract manufacturing organizations and other outside expenses. The Company expenses research and development costs as incurred. The Company expenses upfront, non-refundable payments made for research and development services as obligations are incurred. The value ascribed to intangible assets acquired but which have not met capitalization criteria is expensed as research and development at the time of acquisition.

The Company is required to estimate accrued research and development expenses at each reporting period. This process involves reviewing open contracts and purchase orders, communicating with Company personnel to identify services that have been performed on its behalf and estimating the level of service performed and the associated cost incurred for the service when the Company has not yet been invoiced or otherwise notified of actual costs. The majority of the Company's service providers invoice it in arrears for services performed, on a pre-determined schedule or when contractual milestones are met. However, some require advanced payments. The Company makes estimates of accrued expenses as of each balance sheet date in the financial statements based on facts and circumstances known at that time. The Company periodically confirms the accuracy of the estimates with the service providers and make adjustments, if necessary. Examples of estimated accrued research and development expenses include fees paid to:

- program managers in connection with overall program management of clinical trials;
- CROs in connection with clinical trials; and
- investigative sites in connection with clinical trials.

The Company bases its expenses related to clinical trials on its estimates of the services received and efforts expended pursuant to quotes and contracts with multiple research institutions and CROs that conduct and manage clinical trials on the Company's behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to vendors will exceed the level of services provided and result in a prepayment of the expense. In accruing service fees, the Company estimates the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, the Company adjusts the accrual or prepaid accordingly. Although it does not expect its estimates to be materially different from amounts actually incurred, the Company's understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period. To date, there have not been any material adjustments to the Company's prior estimates of accrued research and development expenses. As of December 31, 2017, the Company has recorded deferred program expense of approximately $33,000 as a component of prepaid expenses and other current assets.

Share-based Payments

Stock options and restricted stock units

The Company grants share-based payments in the form of options and restricted stock units ("RSUs") to employees and non-employees, Joint Share Ownership Plan ("JSOP") awards to employees, as well as agreements to issue common stock in exchange for services provided by non-employees.

Share-based compensation expense is based on the fair value of the option or calculated using the Black-Scholes option pricing model. Determining the appropriate fair value model and related assumptions requires judgment, including estimating share price volatility and expected terms of the awards. The expected volatility rates are estimated based on the actual volatility of the Company and of comparable public companies over the expected term of the option. The expected terms represent the time that options are expected to be outstanding. The Company accounts for forfeitures as they occur and not at the time of grant. The Company has not paid dividends and does not anticipate paying cash dividends in the foreseeable future and, accordingly, uses an expected dividend yield of zero. The risk-free interest rate is based on the rate of U.S. Treasury securities with maturities consistent with the estimated expected term of the awards. Upon exercise, stock options are redeemed for newly issued shares of common stock. RSUs are redeemed for newly issued shares of common stock as the vesting provisions of the grant are met.

For employee options that vest based solely on service conditions, the fair value measurement date is generally on the date of grant and the related compensation expense is recognized on a straight-line basis over the requisite vesting period of the awards.

For non-employee options, the fair value measurement date is the earlier of the date the performance of services is complete or the date the performance commitment has been reached. The Company generally determines that the fair value of the stock options is more reliably measurable than the fair value of the services received. Compensation expense related to stock options granted to non-employees that vest based solely on service conditions is subject to re-measurement at each reporting period until the options vest and is recognized on a straight-line basis over the requisite vesting period of the awards.

The Company adopted Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2016-09, *Compensation – Stock Compensation (Topic 718)* ("ASU 2016-09") effective January 1, 2017. ASU 2016-09 simplifies several aspects of employee share-based payment accounting, including income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. The adoption of this standard did not have a material impact on the Company's financial statements or related disclosures as:

- There have been no stock option exercises as a U.S. company and, therefore, there are no excess tax benefits related to windfalls. Moreover, the Company maintains a full valuation allowance and expects to do so for the foreseeable future;
- The Company has elected to account for forfeitures as they occur, which the Company adopted using a modified retrospective approach and there was no material cumulative effect adjustment to be recorded to opening retained earnings; and
- The Company will classify cash paid to taxing authorities arising from the withholding of shares from employees in cash flows from financing activities.

Common stock awards

The Company grants common stock awards to non-employees in exchange for services provided. The Company measures the fair value of these awards using the fair value of the services provided or the fair value of the awards granted, whichever is more reliably measurable. The fair value measurement date of these awards is generally the date the performance of services is complete. The fair value of the awards is recognized on a straight-line basis as services are rendered. The share-based payments related to common stock awards for the settlement of services provided by non-employees is recorded on the consolidated statement of comprehensive loss in the same manner and charged to the same account as if such settlements had been made in cash.

Warrants

In connection with certain financing, consulting and collaboration arrangements, the Company has issued warrants to purchase shares of its common stock. The outstanding warrants are standalone instruments that are not puttable or mandatorily redeemable by the holder and are classified as equity awards. The Company measures the fair value of the awards using the Black-Scholes option pricing model as of the measurement date. Warrants issued to collaboration partners in conjunction with the issuance of common stock are initially recorded at fair value as a reduction in additional paid-in capital of the common stock issued. All other warrants are recorded at fair value as expense over the requisite service period or at the date of issuance, if there is not a service period. Warrants granted in connection with ongoing arrangements are more fully described in Note 11, *Stockholders' Equity*.

Income Taxes

The Company accounts for income taxes using the asset and liability method. Under this method, deferred tax assets and liabilities are determined based on temporary differences resulting from the different treatment of items for tax and financial reporting purposes. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to reverse. Additionally, the Company must assess the likelihood that deferred tax assets will be recovered as deductions from future taxable income. The Company evaluates the recoverability of its deferred tax assets on a quarterly basis.

Basic and Diluted Net Loss per Share

The Company computes basic net loss per share by dividing net loss applicable to common stockholders by the weighted-average number of shares of common stock outstanding during the period. The Company computes diluted net loss per share after giving consideration to the dilutive effect of stock options that are outstanding during the period, except where such non-participating securities would be anti-dilutive. The Company's JSOP awards, prior to exercise, are considered treasury shares by the Company and thus do not impact the Company's net loss per share calculation. As of December 31, 2017 and 2016, there were approximately 0.3 million JSOP awards issued.

For the years ended December 31, 2017 and 2016, basic and diluted net loss per share are the same for each year due to the Company's net loss position. Potentially dilutive, non-participating securities have not been included in the calculations of diluted net loss per share, as their inclusion would be anti-dilutive. As of December 31, 2017 and 2016, approximately 0.6 million and 1.7 million potentially dilutive securities, respectively, were deemed anti-dilutive.

Segment 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, who is the Company's Chief Executive Officer, in making decisions on how to allocate resources and assess performance. The Company views its operations and manages its business in one operating segment.

Operating Leases

The Company leases administrative and laboratory facilities under operating leases. Lease agreements may include rent holidays, rent escalation clauses and tenant improvement allowances. The Company recognizes scheduled rent increases on a straight-line basis over the lease term beginning with the date the Company takes possession of the leased space.

Acquisitions

The Company has a history of engaging in acquisition transactions that require the Company to evaluate whether the transaction meets the criteria of a business combination and, in some cases, whether it meets the definition of a reverse merger. If the transaction does not meet the business combination requirements, the transaction is accounted for as an asset acquisition or recapitalization and no goodwill is recognized. If the acquisition meets the definition of a business combination, the Company allocates the purchase price, including any contingent consideration, to the assets acquired and the liabilities assumed at their estimated fair values as of the date of the acquisition with any excess of the purchase price paid over the estimated fair value of net assets acquired recorded as goodwill. The fair value of the assets acquired and liabilities assumed is typically determined by using either estimates of replacement costs or discounted cash flow valuation methods.

When determining the fair value of tangible assets acquired, the Company estimates the cost to replace the asset with a new asset, taking into consideration such factors as age, condition and the economic useful life of the asset. When determining the fair value of intangible assets acquired, the Company uses judgment to estimate the applicable discount rate, growth rates and the timing and amount of future cash flows. The fair value of assets acquired and liabilities assumed is typically determined using the assistance of an independent third-party specialist.

Business combination related costs are expensed in the period in which the costs are incurred. Asset acquisition related costs are generally capitalized as a component of cost of the assets acquired.

Recent Accounting Standards

In January 2017, the FASB issued ASU 2017-04: *Intangibles — Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment* that eliminates the requirement to calculate implied fair value of goodwill to measure a goodwill impairment charge. Instead, the new guidance will require entities to take an impairment charge based on the excess of a reporting unit's carrying amount over its fair value. The guidance is effective for the Company no later than 2020. The adoption of this guidance is not expected to have a material impact on the Company's consolidated financial statements.

In November 2016, the FASB issued ASU 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash* that changes the presentation of restricted cash and cash equivalents on the statement of cash flows. Restricted cash and restricted cash equivalents will be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. This amendment is effective for the Company in the fiscal year beginning after December 15, 2017, but early adoption is permissible. The adoption of this guidance is not expected to have a material impact on the Company's consolidated financial statements.

In February 2016, FASB issued ASU 2016-02, *Leases (Topic 842)* ("ASU 2016-02"). ASU 2016-02 will require lessees to recognize a lease liability and a right-of-use asset for all leases, with the exception of short-term leases, at the commencement date. This guidance is effective for annual reporting periods beginning after December 15, 2018, including interim periods within those annual periods. Early application is permitted. The Company is currently evaluating the impact of this new standard.

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)* ("ASU 2014-09"), which supersedes existing revenue recognition guidance. The standard's core principle is that a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods and services. The standard defines a five-step process to achieve this principle and will require companies to use more judgment and make more estimates than under the current guidance. The Company expects that these judgments and estimates will include identifying performance obligations in the customer contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. ASU 2014-09 also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts. The Company does not have any revenue generating contracts with customers and, therefore, the adoption of this new revenue standard will not have a material impact on the consolidated financial statements. The Company adopted the new revenue standard on January 1, 2018 using the modified retrospective approach.

In July 2017, the FASB issued ASU No. 2017-11, *Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815); (Part I) Accounting for Certain Financial Instruments with Down Round Features; (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception* ("ASU 2017-11"). ASU 2017-11 allows companies to exclude a down round feature when determining whether a financial instrument (or embedded conversion feature) is considered indexed to the entity's own stock. As a result, financial instruments (or embedded conversion features) with down round features may no longer be required to be accounted for as derivative liabilities. A company will recognize the value of a down round feature only when it is triggered and the strike price has been adjusted downward. For equity-classified freestanding financial instruments, an entity will treat the value of the effect of the down round as a dividend and a reduction of income available to common shareholders in computing basic earnings per share. For convertible instruments with embedded conversion features containing down round provisions, entities will recognize the value of the down round as a beneficial conversion discount to be amortized to earnings. ASU 2017-11 is effective for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years. Early adoption is permitted. The Company has early adopted ASU 2017-11 and has determined there is no material effect on its consolidated financial statements.

The Company has considered other recent accounting standards and concluded that they are either not applicable to the business, or that no material effect is expected on the consolidated financial statements as a result of future adoption.

3. Acquisitions

2015 Asset Purchase and Financing Agreement

In November 2015, the Company entered into an Asset Purchase Agreement (the "APA") with PJSC Pharmsynthez ("Pharmsynthez") and AS Kevelt ("Kevelt"), a wholly owned subsidiary of Pharmsynthez, providing for the transfer to the Company of certain intellectual property rights with respect to XBIO-101 in exchange for, among other conditions, approximately 3.4 million shares of the Company's common stock. The APA also provided for up to $10.0 million in financing proceeds beginning with the issuance of a minimum of a $3.5 million 10% Senior Secured Collateralized Convertible Promissory Note (the "Initial APA Note") and the issuance of certain warrants covering up to half the amount of the Initial APA Note. Of the approximate 3.4 million total shares exchanged, 0.3 million were issued in December 2015 to two individuals associated with Pharmsynthez and Kevelt and inventors of a provisional patent transferred in connection with the APA.

On April 29, 2016, the Company closed on the APA with an effective date of April 27, 2016, acquiring certain intellectual property rights with respect to the immunomodulator product XBIO-101 held by Kevelt and grant of the worldwide right to develop, market and license XBIO-101 for certain uses, excluding CIS countries. The fair value of the asset acquired was $39.5 million, which included Company common stock issued of $38.6 million and warrants with a fair value of $0.9 million.

In connection with the closing of the APA, Pharmsynthez converted all the then outstanding convertible notes in the principal amount of $6.5 million, which included the Initial APA Note of $3.5 million as well as $3.0 million of notes issued by the Company in July 2015 (plus accrued interest of approximately $0.3 million). The conversion rate as set forth in the notes was $4.95 per share. As such, the Company issued to Pharmsynthez approximately 1.4 million shares of its common stock in connection with conversion of the convertible notes which, together with the approximate 3.0 million shares of common stock issued in connection with the closing of the APA, resulted in an aggregate of 4.4 million new shares of common stock being issued to Pharmsynthez.

4. Significant Strategic Drug Development Collaborations – Related Parties

Shire plc

The Company is party to an exclusive research, development and license agreement with Baxalta US Inc. and Baxalta AB, wholly owned subsidiaries of Shire, related to the development of a novel series of polysialylated blood coagulation factors. This collaboration with Shire relies of the Company's PolyXen technology to conjugate PSA with therapeutic blood-clotting factors, with the goal of improving the pharmacokinetic profile and extending the half-life of these biologic molecules. The agreement grants Shire a worldwide, exclusive, royalty-bearing license to the Company's PSA patented and proprietary technology in combination with Shire's proprietary molecules designed for the treatment of blood and bleeding disorders. The first program under this agreement was a next generation Factor VIII protein product candidate ("SHP656").

In December 2016, Shire reached a milestone of its Phase 1/2 clinical trial for the treatment of hemophilia with SHP656, triggering a $3.0 million payment to be paid to the Company pursuant to the agreement with Shire. The Company determined the milestone to be non-substantive because all significant performance obligations to achieve the contingent payments were the responsibility of Shire with only negligible amount by the Company of effort to fulfill its obligations, specifically assistance on a research committee. As the amount allocable to the remaining performance period was negligible, the Company recognized the full $3.0 million in milestone revenue in connection with this collaboration during the year ended December 31, 2016.

In May 2017 Shire provided an update on the Phase 1/2 clinical study indicating that SHP656's efficacy and pharmacokinetic data commensurate with the profile of an extended half-life rFVIII product. Additionally, to the Company's knowledge, there were no drug-related adverse events, serious adverse events, or rFVIII inhibitors reported. However, the pre-defined once-weekly dosing criterion was not met and the Factor VIII program was terminated by Shire.

On October 27, 2017, the Company entered into the Sublicense Agreement with Baxalta, Pursuant to the Sublicense Agreement, the Company granted to Baxalta the right to grant a nonexclusive sublicense to certain Licensed Patents in connection with the Covered Products. Pursuant to the Sublicense Agreement, Baxalta (i) paid the Company a one-time payment of seven million five hundred thousand dollars ($7,500,000) in November 2017 and (ii) agreed to pay to the Company single digit royalty payments based upon net sales of the Covered Products throughout the Term. The Company recognized the full $7.5 million as license revenue in connection with this Sublicense Agreement during the year ended December 31, 2017.

SynBio LLC

In August 2011, SynBio LLC ("SynBio") and the Company entered into a stock subscription and collaborative development of pharmaceutical products agreement (the "Co-Development Agreement"). The Company granted an exclusive license to SynBio to develop pharmaceutical products using certain molecule(s) based on SynBio's technology and the Company's proprietary technology (PolyXen, OncoHist and ImuXen) that prolongs the active life and/or improves the pharmacokinetics of certain therapeutic proteins and peptides (as well as conventional drugs). In return, SynBio granted an exclusive license to the Company to use the pre-clinical and clinical data generated by SynBio in certain agreed products and engage in the development of commercial candidates.

SynBio and the Company are each responsible for funding their own research activities. There are no milestone or other research-related payments due under the agreement other than fees for the supply of each company's respective research supplies based on their technology, which, when provided, are due to mutual convenience and not representative of an ongoing or recurring obligation to supply research supplies. Serum Institute of India Limited ("Serum Institute") has agreed to directly provide the research supplies to SynBio, where the Company is not liable for any failure to supply the research supplies as a result of any act or fault of Serum Institute. Upon successful commercialization of any resultant products, the Company is entitled to receive royalties on sales in certain territories and pay royalties to SynBio for sales outside those certain territories.

Through December 31, 2017, the Company and SynBio continued to engage in research and development activities with no resultant commercial products. The Company did not recognize revenue in connection with the Co-Development Agreement during the years ended December 31, 2017 and 2016.

SynBio was an affiliate of the Company in 2016 with a share ownership of 9.8% of the total issued common stock of the Company as of December 31, 2016. In addition to its common stock ownership, SynBio also held outstanding warrants to purchase the Company's common stock and all of the Company's issued and outstanding Series A Preferred Stock. In 2017, SynBio became a wholly-owned subsidiary of Pharmsynthez and all ownership percentages previously held by SynBio are combined with Pharmsynthez. See Note 11, *Stockholders' Equity.*

Serum Institute of India Limited

In August 2011, the Company entered into a collaborative research and development agreement with Serum Institute providing Serum Institute an exclusive license to use the Company's PolyXen technology to research and develop one potential commercial product, Polysialylated Erythropoietin ("PSA-EPO"). Serum Institute is responsible for conducting all pre-clinical and clinical trials required to achieve regulatory approvals within the certain predetermined territories at Serum Institute's own expense. Royalty payments are payable by Serum Institute to the Company for net sales to certain customers in the Serum Institute sales territory. Royalty payments are payable by the Company to Serum Institute for net sales received by the Company over the term of the license. There are no milestone or other research-related payments due under the collaborative arrangement.

Through December 31, 2017, the Company and Serum Institute continued to engage in research and development activities with no resultant commercial products. No royalty revenue or expense was recognized by the Company related to the Serum Institute arrangement during the years ended December 31, 2017 and 2016.

Serum Institute is a related party of the Company with a share ownership of approximately 7.2% and 7.5% of the total issued common stock of the Company as of December 31, 2017 and 2016, respectively. In addition to its' common stock ownership, Serum Institute holds outstanding warrants to purchase the Company's common stock. See Note 11, *Stockholders' Equity.*

PJSC Pharmsynthez

In November 2009, the Company entered into a collaborative research and development license agreement with Pharmsynthez (the "Pharmsynthez Arrangement") pursuant to which the Company granted an exclusive license to Pharmsynthez to develop, commercialize and market six drug candidates based on the Company's PolyXen and ImuXen technology in certain territories. In exchange, Pharmsynthez granted an exclusive license to the Company to use any pre-clinical and clinical data developed by Pharmsynthez, within the scope of the Pharmsynthez Arrangement, and to engage in further research, development and commercialization of drug candidates outside of certain territories at the Company's own expense.

In addition to collaborative research and development, the Company and Pharmsynthez engaged in certain financing transactions during 2017 and 2016 which included the issuance by the Company to Pharmsynthez of $4.5 million in promissory notes with warrant coverage during 2016 as well as participation by Pharmsynthez in the Company's November 2016 public offering. For discussion of these transactions refer to Note 8, *Hybrid Debt Instruments*, and Note 11, *Stockholders' Equity.*

Pharmsynthez is an affiliate and controlling stockholder of the Company with a share ownership of approximately 61.5% and 52.6% of the total issued common stock of the Company as of December 31, 2017 and 2016, respectively. In addition to its common stock ownership, Pharmsynthez holds outstanding warrants to purchase the Company's common stock, approximately 1.5 million shares of the Company's issued and outstanding Series B Preferred Stock, and all of the Company's issued and outstanding Series A Preferred Stock through its wholly-owned subsidiary, SynBio. See Note 11, *Stockholders' Equity*.

5. Property and Equipment, net

Property and equipment, net consists of the following:

	December 31, 2017	December 31, 2016
Laboratory equipment	$ 264,583	$ 264,583
Office and computer equipment	46,634	37,370
Leasehold improvements	26,841	26,841
Furniture and fixtures	20,263	20,263
Property and equipment	358,321	349,057
Less accumulated depreciation	(330,475)	(306,691)
Property and equipment – net	$ 27,846	$ 42,366

Depreciation expense was approximately $24,000 and $36,000 for the years ended December 31, 2017 and 2016, respectively.

6. Goodwill and Indefinite-Lived Intangible Assets

Goodwill

A reconciliation of the change in the carrying value of goodwill is as follows:

Balance as of January 1, 2016	$ 3,283,379
No changes	–
Balance as of December 31, 2016	$ 3,283,379
No changes	–
Balance as of December 31, 2017	$ 3,283,379

As of October 1, 2017 and 2016, the dates of the Company's annual impairment review, the fair value of the Company's goodwill balance exceeded its carrying value.

Indefinite-Lived Intangible Assets

The Company's acquired indefinite-lived intangible asset, OncoHist, is IPR&D relating to the Company's business combination with SymbioTec in 2012. The carrying value of OncoHist was approximately $9.2 million as of December 31, 2017 and 2016. No impairment was recorded during the years ended December 31, 2017 and 2016. OncoHist is not yet commercialized and, therefore, has not yet begun to be amortized as of December 31, 2017.

7. Accrued Expenses

Accrued expenses consist of the following:

	December 31, 2017	December 31, 2016
Accrued payroll and benefits	$ 723,488	$ 109,315
Accrued professional fees	389,086	477,345
Accrued research costs	11,477	208,751
Other	11,602	43,477
	$ 1,135,653	$ 838,888

On November 2, 2017, the Company entered into a Settlement Agreement with M. Scott Maguire, former Chief Executive Officer of the Company (the "Settlement Agreement"), which terminated the Employment Agreement dated November 3, 2009, between Xenetic UK and Mr. Maguire. Pursuant to the terms of the Settlement Agreement, Mr. Maguire will continue to receive his current base salary and benefits for a period of 12 months, received a lump sum termination payment of £30,000 and will be reimbursed for certain tax liabilities as described in the Settlement Agreement. As of December 31, 2017, the Company expensed approximately $0.4 million of accrued payroll and benefits related to future payments required to be made to Mr. Maguire in accordance with the Settlement Agreement. Additionally, Mr. Maguire's unvested stock options will immediately vest on October 31, 2018, upon the terms and conditions specified in the Settlement Agreement, and Mr. Maguire will have until June 10, 2020 to exercise the vested options.

8. Hybrid Debt Instruments

During 2015 and 2016, the Company entered into several financing arrangements which included the issuance of convertible notes and warrants to purchase shares of common stock.

On July 1, 2015, the Company entered into a Securities Purchase Agreement (the "SPA") with Pharmsynthez providing for the issuance of a minimum of a $3.0 million 10% Senior Secured Collateralized Convertible Promissory Note (the "SPA Note"). The SPA also provided for the issuance of certain warrants up to the amount of the SPA Note to purchase shares of common stock at the lesser of $6.60 per share and 120% of the price per share in the Company's next capital raise of at least $7 million (the "Exercise Price").

On November 13, 2015, the Company entered into the APA with Pharmsynthez and Kevelt providing for, among other things, the issuance of a minimum of a $3.5 million 10% Senior Secured Collateralized Convertible Promissory Note (the "Initial APA Note") and the issuance of certain warrants. The warrants covered up to half the amount of the Initial APA Note to purchase shares of common stock at the Exercise Price. During the quarter ended March 31, 2016, the Company issued $3.5 million of convertible debt as well as the associated warrants, both in connection with the Initial APA Note. A $1.6 million loss was recorded upon the issuance of hybrid debt instruments. In addition, a $1.9 million gain was recorded during 2016 reflecting the change in fair value of hybrid instruments during the period.

On April 22, 2016, Pharmsynthez converted all of the then outstanding convertible notes issued by the Company to Pharmsynthez in the principal amount of $6.5 million plus accrued interest of approximately $0.2 million, resulting in a $6.2 million loss. The conversion rate was $4.95 per share. As such, the Company issued to Pharmsynthez approximately 1.4 million shares of common stock in connection with conversion of the convertible notes. The related embedded derivatives, which had been bifurcated from the host debt and accounted for separately, were settled by action of the conversion. Both the final mark-to-market gain and the loss on conversion were recorded in other income (expense) in the consolidated statement of comprehensive loss for the year ended December 31, 2016.

On July 1, 2016, the Company issued a convertible promissory note (the "Note") in the amount of $500,000 to Pharmsynthez. In consideration for the Note, the Company issued Pharmsynthez warrants (the "Warrants") to purchase 50,506 shares of its common stock at the Exercise Price. The Note was convertible into shares of the Company's common stock at any time at a conversion price of $4.95 per share (subject to price protection and usual and customary adjustments). The Warrants could be exercised at any time through the five-year anniversary. The maturity date of the Note was one year from issuance and was convertible, in whole or in part, into shares of common stock at the option of the holder, at any time and from time to time in accordance with the terms contained therein. Upon a public offering, as such term was defined in the Note, the holder was required to convert the Note to shares of the Company's common stock in accordance with the conversion terms contained therein.

On July 1, 2016, the Company issued a convertible promissory note in the amount of $369,958 (the "CEO Note") and warrants to purchase 37,369 shares of the Company's common stock at the Exercise Price to Mr. Scott Maguire, the Company's former CEO, for his deferred salary. Upon a public offering, as defined, and at the option of the holder, the CEO Note could be settled in cash or by means of conversion into shares of common stock in accordance with the conversion terms contained therein. Upon completion of its public offering, the Company settled the CEO Note and the related interest of $13,176 in cash on November 7, 2016.

On August 26 and September 9, 2016, the Company issued convertible promissory notes (the "Further Notes") in the amount of $178,000 and $322,000, respectively, and warrants to purchase 50,506 shares of its common stock at the Exercise Price to Pharmsynthez. The notes were convertible into shares of the Company's common stock at any time at a conversion price of $4.00 per share (subject to price protection and usual and customary adjustments) or may be applied toward a public offering, at the option of Pharmsynthez. The maturity date of the Further Notes was one year from issuance and were convertible, in whole or in part, into shares of common stock at the option of the holder, at any time and from time to time in accordance with the terms contained therein. Upon the closing of the Company's underwritten public offering in November 2016, the balance of the Further Notes automatically converted into units of the Company's public offering in accordance with the conversion terms contained therein.

The Note, CEO Note and Further Notes (together, the "Period Notes") shared the same principal terms and features. The Period Notes were convertible debt and included embedded debt-like features and were reflected as a hybrid debt instrument.

The fair value of the compound derivative was bifurcated from the Period Notes and remeasured at each report date until they were settled, with changes in fair value recognized in the consolidated statement of comprehensive loss as a change in fair value of derivative liability. Refer to Note 9, *Fair Value Measurements*, for a table showing changes in the combined compound derivative during the year ended December 31, 2016.

The key assumptions used to calculate the estimated fair value of the compound derivative liability at each issuance and subsequent report date included the Company's stock price ($4.50 - $16.83), expected volatility (100% - 115%), and risk-free interest rate (0.28% - 0.68%).

A $0.1 million loss on issuance of hybrid instrument was recorded upon the issuance of the Period Notes. This amount was recorded as a loss in other income (expense) in the consolidated statement of comprehensive loss for the year ended December 31, 2016.

On November 7, 2016, the Company closed an approximate $10.0 million underwritten public offering (see Note 11, *Stockholders' Equity*). In connection with the offering and pursuant to the respective terms therein, the balances of the Period Notes were settled as follows:

- The Note converted to shares of common stock,
- The CEO Note was settled in cash, and
- The Further Notes converted into units which are included in the aggregate 2,424,242 offering units discussed in Note 11, *Stockholders' Equity*.

Following the November 2016 settlement of these instruments, all outstanding convertible debt and embedded debt-like instruments under these financing arrangements were retired. As a result, no hybrid debt instruments were outstanding as of December 31, 2017 and December 31, 2016, respectively. Interest expense (including both debt discount amortization and coupon rate) related to the SPA Note, the Initial APA Note, and the Period Notes of approximately $0.7 million was recognized in the consolidated statement of comprehensive loss for the twelve months ended December 31, 2016.

9. Fair Value Measurements

ASC Topic 820, *Fair Value Measurement,* defines fair value as the price that would be received to sell an asset or be paid to transfer a liability in an orderly transaction between market participants at the measurement date. The Company applies the following fair value hierarchy, which prioritizes the inputs used to measure fair value into three levels and bases the categorization within the hierarchy upon the lowest level of input that is available and significant to the fair value measurement. Level 1 inputs are quoted prices in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date. Level 2 utilizes quoted market prices in markets that are not active, broker or dealer quotations, or alternative pricing sources with reasonable levels of price transparency. Level 3 inputs are unobservable inputs for the asset or liability in which there is little, if any, market activity for the asset or liability at the measurement date.

The Company's cash and restricted cash are measured at fair value and are classified as Level 1 in the fair value hierarchy. The carrying amount of certain of the Company's financial instruments approximate fair value due to their short maturities. The Company measures derivative liabilities at fair value on a recurring basis and classifies derivative liabilities as Level 3 in the fair value hierarchy.

There were no financial instruments classified as Level 3 in the fair value hierarchy during the year ended December 31, 2017. The following table provides a summary of the changes in fair value of the compound derivative instrument measured at fair value on a recurring basis using significant unobservable inputs during the year ended December 31, 2016.

Balance as of January 1, 2016	$	(3,544,222)
Issuance of compound derivative instrument		(4,120,359)
Change in fair value of compound derivative instrument		2,125,113
Settlement of derivative instruments through conversion of debt host		5,539,468
Balance as of December 31, 2016	$	–

10. Income Taxes

Deferred tax assets and liabilities are determined based on temporary differences resulting from the different treatment of items for tax and financial reporting purposes. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to reverse. Additionally, the Company must assess the likelihood that deferred tax assets will be recovered as deductions from future taxable income. The Company has provided a full valuation allowance on the Company's deferred tax assets because the Company believes it is more likely than not that its deferred tax assets will not be realized. The Company evaluates the recoverability of its deferred tax assets on a quarterly basis. Currently, there is no provision for income taxes as the Company has incurred losses to date.

The components of loss before income taxes are as follows:

	Year ended December 31,	
	2017	2016
Domestic (U.S.)	$ (5,889,926)	$ (12,253,271)
Foreign (U.K.)	2,398,830	(41,837,056)
Foreign (Germany)	(104,036)	(115,779)
Loss before income taxes	$ (3,595,132)	$ (54,206,106)

The reconciliation of income tax benefit at the U.S. corporation tax rate, being the rate applicable to the country of domicile of the Company to net income tax benefit is as follows:

	Year ended December 31,	
	2017	2016
Federal	$ (1,222,345)	(18,429,763)
State	(303,315)	(455,191)
Increase in tax losses not recognized	(359,833)	9,751,401
Permanent differences, net	162,543	780,836
Mark to market	–	992,621
Foreign rate differential	(383,601)	6,923,116
Share-based payments, net	(22,087)	524,131
Changes per enacted tax reform	2,320,059	–
Enhanced research and development tax credits	(191,421)	(87,151)
Net provision (benefit) for income taxes	$ –	$ –

Deferred tax assets and liabilities reflect the net tax effect of temporary differences between the carrying amount of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets are as follows:

	Year ended December 31,	
	2017	2016
Deferred tax assets:		
U.K. net operating loss carryforwards	$ 7,641,719	$ 6,868,717
U.K. capital loss carryforwards	1,378,643	1,259,062
U.S. federal net operating loss carryforwards	2,606,017	3,061,669
IPR&D	6,776,473	6,630,745
Share-based payments	1,527,615	1,534,992
Enhanced research and development tax credits	1,060,200	796,256
Germany net operating loss carryforwards	516,401	424,432
U.S. state net operating loss carryforwards	1,057,856	749,812
Accrued expenses	198,067	174,424
Depreciation	1,948	3,673
Other	–	–
Total deferred tax assets before valuation allowance	22,764,939	21,503,782
Valuation allowance for deferred tax assets	(22,764,939)	(21,503,782)
Deferred tax liabilities:		
Indefinite-lived intangible asset	(2,918,518)	(2,918,518)
Debt discount	–	–
Total deferred tax liabilities	(2,918,518)	(2,918,518)
Net deferred tax assets and liabilities	$ (2,918,518)	$ (2,918,518)

For the years ended December 31, 2017 and 2016, the Company had U.K. net operating loss carryforwards of approximately $45.0 million and $41.1 million, respectively, U.S. federal net operating loss carryforwards of approximately $13.5 million and $9.8 million, respectively, U.S. state net operating loss carryforwards of approximately $13.3 million and $9.4 million, respectively, and Germany net operating loss carryforwards of approximately $1.6 million and $1.3 million, respectively. The U.K. and Germany net operating loss carryforwards can be carried forward indefinitely. The U.S. federal and state net operating loss carryforwards begin to expire in 2032.

The Company's ability to use its operating loss carryforwards and tax credits generated in the U.S. to offset future taxable income is subject to restrictions under Section 382 of the United States Internal Revenue Code (the "Internal Revenue Code"). These restrictions may limit the future use of the operating loss carryforwards and tax credits if certain ownership changes described in the Internal Revenue Code occur. Future changes in stock ownership may occur that would create further limitations on the Company's use of the operating loss carryforwards and tax credits. In such a situation, the Company may be required to pay income taxes, even though significant operating loss carryforwards and tax credits exist.

The Company's ability to use its operating loss carryforwards and tax credits generated in the U.K. are subject to restrictions under U.K. tax legislation. These regulations may limit the future use of operating loss carryforwards if there is a change in ownership and a change in the nature or conduct of the business carried on by the Company, and in certain circumstances where there is a change in the nature or conduct of the business only. In such cases the carryforwards would cease to be available to set against future income.

The Company's ability to use its operating loss carryforwards and tax credits generated in Germany are also subject to restrictions under German tax legislation. These regulations may limit the future use of operating loss carryforwards if there is a change in ownership. In such cases the carryforwards would cease to be available to set against future income.

On December 22, 2017, the United States enacted new tax reform ("Tax Cuts and Jobs Act"). The Tax Cuts and Jobs Act contains provisions with separate effective dates but is generally effective for taxable years beginning after December 31, 2017. Beginning with the year ending December 31, 2018, the corporate statutory rates on U.S. earnings will be reduced from 34% to 21%. The impact of the future rate reduction for the year ending December 31, 2017, was approximately $2.3 million relating to the revaluation of the net deferred tax assets. Other than the reduction in statutory rate, the Company does not anticipate the regulations will have a material impact on income taxes in future years. The Tax Cuts and Jobs Act also contains a provision requiring companies to repatriate all aggregate post 1986 earnings and profits of foreign corporations. The Company has estimated that the repatriation will be zero under a provisional basis under SAB118.

As discussed in Note 2, Summary of Significant Accounting Policies, the Company adopted ASU 2016-09, Compensation - Stock Compensation (Topic 718): Improvement to Employee Share-Based Payment Accounting. Upon adoption of this standard in 2017, the Company has recognized their previously unrecognized excess tax benefits, which resulted in a cumulative-effect increase of $0.1 million to their deferred tax assets along with an increase to the corresponding valuation allowance against these deferred tax assets.

As of December 31, 2017 and 2016, the Company did not record any uncertain tax positions. The changes to uncertain tax positions for 2017 and 2016 were as follows:

	Year ended December 31,	
	2017	2016
Uncertain tax benefits as of January 1	$ –	$ –
Gross adjustments in tax positions	–	–
Uncertain tax positions as of December 31	$ –	$ –

The Company files income tax returns in the U.S. federal tax jurisdiction and Massachusetts state tax jurisdiction, and certain foreign tax jurisdictions. The Company is subject to examination by the U.S. federal, state, foreign, and local income tax authorities for calendar tax years ending 2012 through 2017 due to available net operating loss carryforwards and research and development tax credits arising in those years. The Company has not been notified of any examinations by the Internal Revenue Service or any other tax authorities as of December 31, 2017. The Company has not recorded any interest or penalties for unrecognized tax benefits since its inception.

Potential 382 Limitation

The Company's net operating loss and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service. The Company's ability to utilize its net operating loss ("NOL") and research and development credit ("R&D") carryforwards may be substantially limited due to ownership changes that may have occurred or that could occur in the future, as required by Section 382 of the Internal Revenue Code of 1986, as amended (the "Code"), as well as similar state provisions. These ownership changes may limit the amount of NOL and R&D credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. In general, an ownership change, as defined in Section 382 of the Code, results from a transaction or series of transactions over a three-year period resulting in an ownership change of more than 50% of the outstanding stock of a company by certain stockholders or public groups.

The Company has not completed a study to assess whether one or more ownership changes have occurred since it became a loss corporation as defined in Section 382 of the Code, but the Company believes that it is likely that an ownership change has occurred. If the Company has experienced an ownership change, utilization of the NOL and R&D credit carryforwards would be subject to an annual limitation, which is determined by first multiplying the value of the Company's common stock at the time of the ownership change by the applicable long-term, tax-exempt rate, and then could be subject to additional adjustments, as required. Any such limitation may result in the expiration of a portion of the NOL or R&D credit carryforwards before utilization. Until a study is completed, and any limitation known, no amounts are being considered as an uncertain tax position or disclosed as an unrecognized tax benefit. Any carryforwards that expire prior to utilization as a result of such limitations will be removed from deferred tax assets with a corresponding adjustment to the valuation allowance. Due to the existence of the valuation allowance, it is not expected that any potential limitation will have a material impact on the Company's operating results.

From time to time the Company may be assessed interest or penalties by major tax jurisdictions, namely the Commonwealth of Massachusetts. As of December 31, 2017, the Company had no material unrecognized tax benefits and no adjustments to liabilities or operations were required. No interest and penalties have been recognized by the Company to date.

The Company net operating loss carryforwards are subject to review and possible adjustment by the Internal Revenue Service and are subject to certain limitations in the event of cumulative changes in the ownership interest of significant stockholders over a three-year period in excess of 50%.

11. Stockholders' Equity

Reverse Stock Split

On May 16, 2016, the Company's board of directors approved a reverse stock split on a 1 for 33 basis, in the Company's authorized common stock, along with a corresponding and proportional decrease in the number of shares of the Company's common stock issued and outstanding. This reduction was filed with the Nevada Secretary of State on May 18, 2016 but required a review by the Financial Industry Regulatory Authority, Inc. ("FINRA") before becoming effective in the market. On May 31, 2016, FINRA announced that this change took effect in the over-the-counter securities markets on June 1, 2016.

All share information provided herein reflects the effect of the reverse stock split for all periods presented.

Public Offering

On November 7, 2016, the Company closed its public offering of an aggregate of 2,424,242 units, consisting of (i) 484,849 units, consisting of one share of Convertible Series B Preferred Stock and a Class A Warrant to purchase one share of common stock and (ii) 1,939,393 units consisting of one share of Convertible Series B Preferred Stock and a Class B Warrant to purchase one share of common stock, at a public offering price of $4.125 per unit (the "Public Offering"). At closing, the Company issued $10.0 million of units and received $9.0 million in cash, which is net of approximately $0.5 million in underwriting and related fees as well as proceeds from the Further Notes of $0.5 million, which automatically converted into units of the Public Offering on a one-for-one basis.

The Company assessed the Public Offering warrants as meeting the criteria for equity classification and allocated the proceeds based on the relative fair values of the base instruments (the Series B preferred stock and the warrants). The Company obtained a valuation of the Series B preferred stock and associated warrants, which indicated values of $5.23 and $3.45, respectively.

The Company determined that the embedded conversion feature of the Series B preferred stock included more equity-like features than debt-like features and, therefore, concluded that the conversion feature should not be bifurcated and accounted for separately.

In addition, the Company evaluated the conversion feature of the Series B preferred stock to assess whether it met the definition of a beneficial conversion feature ("BCF"). The initial conversion price per share for each share of Series B preferred stock is equal to $4.00 per share and the exercise price of the warrant is equal to $4.00 per share. As the fair value of a share of common stock of $4.15 exceeded the effective conversion price of $2.49 at the issuance date, the Series B preferred stock contained a BCF. The total intrinsic value of the BCF of approximately $4.0 million was recorded as a discount to the preferred stock and a credit to additional paid in capital. Because the Series B preferred stock has no redemption date and is immediately convertible, the BCF was immediately accreted.

Common Stock

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Common stockholders are entitled to dividends when and if declared by the Board of Directors. In the event of any voluntary or involuntary liquidation, dissolution or winding-up of the Company, the holders of common stock are entitled to share ratably in the assets of the Company available for distribution.

In December 2015, approximately 0.3 million shares of new common stock were issued to Dr. Genkin and Mr. Surkhov, individuals associated with Pharmsynthez and Kevelt and inventors of a provisional patent transferred in connection with the APA.

On April 29, 2016, the Company closed on the APA with an effective date of April 27, 2016, acquiring IPR&D related to certain intellectual property rights with respect to the immunomodulator product XBIO-101 held by Kevelt. In connection with the closing, the Company issued approximately 3.1 million shares of its common stock to Pharmsynthez. The fair value of the asset acquired was $39.5 million, which was determined to be more reliably measured than the related equity consideration. As there was no alternative use for the IPR&D, the Company recognized $39.5 million of expense in the Statement of Comprehensive Loss for the year ended December 31, 2016.

On September 15, 2016, the Company issued approximately 0.2 million shares of common stock to Serum Institute in exchange for approximately $0.8 million of clinical PSA supply as well as settlement of approximately $0.2 million of prior purchases of PSA supply. Approximately $0.1 million of the clinical supply was expensed during the twelve months ended December 31, 2017. The remaining $0.7 million was reclassified to long-term as the Company does not anticipate utilizing the majority of the PSA supply within the next 12-months.

On September 23, 2016, SynBio exchanged approximately 1.0 million shares of common stock in the Company for an equal number of shares of Series A Preferred Stock.

In March 2017, the Company issued approximately 0.1 million shares of the Company's common stock to Pharmsynthez in connection with the conversion of the Note as a result of the Company's underwritten public offering in November 2016 and Pharmsynthez subsequently exercising its rights to the shares. The shares issued to Pharmsynthez represent both owed principal and accrued interest.

The holders of Series B Convertible Preferred Stock converted approximately 0.2 million shares and 0.1 million shares into the same number of shares of common stock during the years ended December 31, 2017 and December 31, 2016, respectively.

Series A Preferred Stock

As approved by the Company's Board of Directors, the Company filed with the Secretary of State of the State of Nevada a Certificate of Designation of Series A Preferred Stock and subsequently filed an Amended and Restated Certificate of Designation of Series A Preferred Stock (the "Amended Series A Certificate of Designation") on October 27, 2016. Pursuant to the Amended Series A Certificate of Designation, the Company designated 1,000,000 shares as Series A preferred stock. Each share of Series A preferred stock has a par value of $0.001 and stated value of $4.80.

The following is a summary of the material terms of the Series A preferred stock.

Liquidation. Upon any dissolution, liquidation or winding up, whether voluntary or involuntary, holders of Series A preferred stock will be entitled to receive distributions out of the Company's assets, of an amount equal to $4.80 per share of Series A preferred stock (as adjusted for stock splits, combinations, reorganizations and the like) plus any accrued and unpaid dividends thereon before any distributions shall be made on the common stock or any series of preferred stock ranked junior to the Series A preferred stock.

Dividends. Holders of the Series A preferred stock are entitled to receive a non-cumulative, annual cash dividend of $0.24 per share of Series A Preferred Stock, when and if declared by the Company's Board, out of the Company's assets legally available therefore. No dividends or other distribution will be made on the common stock or any series of preferred stock ranked junior to the Series A preferred stock unless the dividend on the Series A Preferred Stock has been paid current and a reserve has been made for the next calendar year. The Company's ability to pay dividends on Series A preferred stock is subject to restrictions in the Company's Series B preferred stock, which ranks senior to the Series A preferred stock in right of payment.

Conversion. Each share of Series A preferred stock is convertible, at any time and from time to time at the option of the holder thereof, with a minimum of 61 days' advance notice to the Company, into one share of common stock.

Stock Dividends and Stock Splits. If Xenetic pays a stock dividend or otherwise make a distribution payable in shares of common stock on shares of common stock or any other common stock equivalents, subdivide or combine outstanding common stock, or reclassify common stock, the conversion rate will be adjusted to match the conversion rate immediately before such event.

Fundamental Transaction. If Xenetic effects a reorganization, undergo a change in control event, or enter into any plan or arrangement contemplating the Company's dissolution, then upon any subsequent conversion of Series A preferred stock, the holder thereof shall have the right to receive, for each share of common stock that would have been issuable upon such conversion immediately prior to the occurrence of such transaction, the number of shares of the successor's or acquiring corporation's common stock or of the Company's common stock, if Xenetic is the surviving corporation, and any additional consideration receivable as a result of such transaction by a holder of the number of shares of common stock into which Series A preferred stock is convertible immediately prior to such transaction. A change in control event means a sale of all or substantially all of the Company's assets or an acquisition of the Company by another entity by means of any transaction or series of related transactions (including, without limitation, a reorganization, consolidated or merger) that results in the transfer of fifty percent (50%) or more of the outstanding voting power of the Company.

Voting Rights. Except as otherwise provided in the Series A Preferred Stock amended and restated certificate of designation or required by law, the Series A Preferred Stock has no voting rights. The holders of Series A Preferred Stock have voting rights as to proposals that specifically affect their shares by law, in which they will vote separately and the vote necessary to approve such proposals will be as set by law.

Fractional Shares. No fractional shares of common stock will be issued upon conversion of Series A preferred stock. Rather, the Company will round up to the next whole share.

Redemption. At any time after December 31, 2016, upon 30 days prior written notice, the Company may require the holder of any Series A Preferred Stock to convert any or all of such holder's Series A preferred stock to common stock at a rate of one share of Series A Preferred Stock to one share of common stock.

As of December 31, 2017 and 2016, there were approximately 1.0 million shares of Series A preferred stock issued and outstanding which are convertible into the same number of shares of common stock.

Series B Preferred Stock

In connection with the Public Offering and as approved by the Company's Board of Directors, the Company filed with the Secretary of State of the State of Nevada a Certificate of Designation of Series B Preferred Stock and subsequently filed an Amended and Restated Certificate of Designation of Series B Preferred Stock (the "Amended Series B Certificate of Designation"). Pursuant to the Amended Series B Certificate of Designation, the Company designated 2,500,000 shares as Series B preferred stock. Each share of Series B preferred stock has a stated value of $4.00 per share.

The following is a summary of the material terms of the Company's Series B Preferred Stock.

Liquidation. Upon any dissolution, liquidation or winding up, whether voluntary or involuntary, holders of Series B Preferred Stock will be entitled to receive distributions out of the Company's assets, of an amount equal to $4.00 per share of Series B Preferred Stock (as adjusted for stock splits, combinations, reorganizations and the like) plus any accrued and unpaid dividends thereon and any other fees or liquidated damages then due and owing thereon under the amended and restated certificate of designation before any distributions shall be made on the common stock or any series of preferred stock ranked junior to the Series B Preferred Stock, which includes Series A Preferred Stock. A fundamental transaction or change of control under the amended and restated certificate of designation shall constitute a liquidation for purposes of this right. Xenetic will give each holder of Series B Preferred Stock written notice of any liquidation at least 30 days before any meeting of stockholders to approve such liquidation or at least 45 days before the date of such liquidation if no meeting is to be held.

Dividends. Subject to any preferential rights of any outstanding series of preferred stock created by the Company's Board from time to time, the holders of shares of the Company's Series B Preferred Stock will be entitled to such cash dividends, non-cumulative, as may be declared from time to time by the Company's Board on shares of the Company's common stock (on an as-converted basis) from funds available therefore. The Company shall not directly or indirectly pay or declare any dividend or make any distribution upon, nor shall any distribution be made in respect of, any junior securities, including Series A preferred stock, as long as any dividends due on the Series B preferred stock remain unpaid, nor shall any monies be set aside for or applied to the purchase or redemption of any junior securities or shares pari passu with the Series B preferred stock.

Conversion. Each share of Series B Preferred Stock is convertible, at any time and from time to time at the option of the holder thereof, into one share of common stock, subject to the adjustments described below.

Stock Dividends and Stock Splits. If Xenetic pays a stock dividend or otherwise make a distribution payable in shares of common stock on shares of common stock or any other common stock equivalents, subdivide or combine outstanding common stock, or reclassify common stock, the conversion rate will be adjusted to match the conversion rate immediately before such event.

Fundamental Transaction. If Xenetic effects a reorganization, undergo a change in control event, or enter into any plan or arrangement contemplating the Company's dissolution, then upon any subsequent conversion of Series B preferred stock, the holder thereof shall have the right to receive, for each share of common stock that would have been issuable upon such conversion immediately prior to the occurrence of such transaction, the number of shares of the successor's or acquiring corporation's common stock or of the Company's common stock, if Xenetic is the surviving corporation, and any additional consideration receivable as a result of such transaction by a holder of the number of shares of common stock into which Series B preferred stock is convertible immediately prior to such transaction. A change in control event means a sale of all or substantially all of the Company's assets or an acquisition of the Company by another entity by means of any transaction or series of related transactions (including, without limitation, a reorganization, consolidated or merger) that results in the transfer of thirty-three percent (33%) or more of the outstanding voting power of the Company, with the exception of acquisition of additional voting capital stock by Pharmsynthez or its affiliates.

Subsequent Equity Sales. The Series B Preferred Stock has full ratchet price based anti-dilution protection, subject to shareholder approval and customary carve outs, in the event of a down-round financing at a price per share below the stated value of the Series B Preferred Stock.

Voting Rights. Except as otherwise provided in the Series B Preferred Stock second amended and restated certificate of designation or required by law, the Series B Preferred Stock has no voting rights. However, as long as any Series B Preferred Stock remains outstanding, the amended and restated certificate of designation provides that the Company shall not, without the affirmative vote of all then-outstanding Series B Preferred Stock, (a) alter or change adversely the powers, preferences or rights given to the Series B Preferred Stock or alter or amend the certificate of designation, (b) authorize or create any class of stock ranking as to dividends, redemption or distribution of assets upon a liquidation senior to, or otherwise pari passu with, the Series B Preferred Stock, (c) amend its certificate of incorporation or other charter documents in any manner that adversely affects any rights of the holders of Series B Preferred Stock, (d) increase the number of authorized shares of Series B Preferred Stock, or (e) enter into any agreement with respect to any of the foregoing. The holders of Series B Preferred Stock have voting rights as to proposals that specifically affect their shares by law, in which they will vote separately and the vote necessary to approve such proposals will be as set by law.

Fractional Shares. No fractional shares of common stock will be issued upon conversion of Series B Preferred Stock. Rather, the Company will, at its election, round up to the next whole share or pay a cash adjustment.

Pursuant to the Public Offering, the Company issued approximately 2.4 million shares of Series B preferred stock. Since its issuance on November 7, 2016, holders of Series B preferred stock converted 0.3 million shares to the same number of common stock shares. As of December 31, 2017, there were approximately 2.1 million shares of Series B preferred stock issued and outstanding which are convertible into the same number of shares of common stock.

Warrants Related to Collaboration and Consulting Agreements

As of December 31, 2017 and 2016 there were outstanding warrants related to collaboration and consulting agreements to purchase an aggregate of 646,249 shares of common stock at an average weighted exercise price of $12.89. These warrants are fair valued at issuance date using the Black-Scholes option pricing model. The warrants are subject to re-measurement at each reporting period until the measurement date is reached. Expense is recognized on a straight-line basis over the expected service period or at the date of issuance, if there is not a service period.

On December 31, 2014, SynBio was granted a warrant to purchase 204,394 new shares of common stock at an exercise price of $25.41 per share ("SynBio 2014 Warrant"). The SynBio 2014 Warrant is exercisable in four equal tranches, each with separate non-market, performance-based vesting criteria. The Company uses its judgment to assess the probability and timing of SynBio achieving these vesting criteria and estimated that it is not probable that the vesting criteria for any tranche will be achieved. As a result, the Company did not recognize expense related to this warrant during the years ended December 31, 2017 and 2016. These judgments are reassessed at each reporting period until the measurement date is reached.

In connection with the SynBio 2014 Warrant grant, warrants to purchase 9,697 aggregate new shares of common stock were issued to SynBio and Pharmsynthez non-director designees ("SynBio Partner Warrants") on December 31, 2014 under the same terms and conditions of the SynBio 2014 Warrant. The Company estimated that it is not probable that the vesting criteria for any tranche will be achieved and, as a result, the Company did not recognize expense related to the SynBio Partner Warrants during the years ended December 31, 2017 and 2016. The SynBio 2014 Warrant and SynBio Partner Warrants expire on December 30, 2019 and no warrants were exercised during the years ended December 31, 2017 and 2016.

On December 31, 2014, the Company granted Serum Institute a warrant to purchase 96,970 new shares of common stock at an exercise price of $25.41 per share ("Serum Institute 2014 Warrant"). The Serum Institute 2014 Warrant, which was fair valued at approximately $0.5 million at the time of issuance, is exercisable in two equal tranches, each with separate non-market, performance-based vesting criteria. The Company uses its judgment to assess the probability and timing of Serum Institute achieving these vesting criteria and estimated that it is probable that the vesting criteria will be achieved for each tranche. These judgments are reassessed at each reporting period until the measurement date is reached.

In connection with the Serum Institute 2014 Warrant grant, warrants to purchase 4,852 aggregate new shares of common stock were issued to Serum Institute non-director designees ("Serum Institute Partner Warrants") on December 31, 2014 under the same terms and conditions of the Serum Institute 2014 Warrant. The Serum Institute Partner Warrants were fair valued at approximately $24,000 at the time of issuance.

On May 16, 2016, the Company modified the exercise price of 150,307 performance-based warrants held by Serum Institute and individuals related to Serum Institute from $25.41 to $7.92 which resulted in an incremental value expense of approximately $0.2 million.

Additionally, the Company issued 212,122 warrants to purchase shares of common stock to Serum Institute with an exercise price of $7.92. The new warrants were fully vested and the Company recognized $1.4 million in research and development expense in the consolidated statements of comprehensive loss related to the grants.

The Company recognized warrant (income) expense of approximately $(0.1) million and $1.1 million during the years ended December 31, 2017 and 2016, respectively, related to the Serum Institute 2014 Warrant and Serum Institute Partner Warrants. The Serum Institute 2014 Warrant and Serum Institute Partner Warrants expire on December 30, 2019. No warrants were exercised during the years ended December 31, 2017 and 2016 and no warrants were granted during the year ended December 31, 2017. Key assumptions used in the Black-Scholes option pricing model for warrants related to collaboration and consultant agreements granted during the year ended December 31, 2016 are as follows:

	2016
Weighted-average expected dividend yield (%)	–
Weighted-average expected volatility (%)	109.86
Weighted-average risk-free interest rate (%)	0.97
Weighted-average expected life of option (years)	5.00
Weighted-average exercise price ($)	10.40

Warrants Related to Financing Arrangements

As of December 31, 2017 and 2016 there were outstanding warrants related to financing agreements to purchase an aggregate of 3,522,225 shares of Common Stock at an average weighted exercise price of $4.30.

In connection with the Company's issuance of the SPA Note on July 1, 2015, the Company issued a warrant to purchase 303,031 shares of common stock in accordance with the terms of the SPA (the "SPA Warrant"). The SPA Warrant has a five-year term and is exercisable commencing January 1, 2016, at the Exercise Price. Pursuant to the terms of the SPA Note, if not repaid or converted on or before six months from the date of issuance, the Holder will be issued an additional warrant to purchase 303,031 shares of common stock under the same terms as the Warrant (the "Contingent SPA Warrant," or together referred to as the "SPA Warrants"). The Company determined there was a high probability that the SPA Note would not be repaid or converted within the period six months from the date of issuance, resulting in the issuance of the Contingent Warrant. As such, the Company concluded the Contingent SPA Warrant to be considered issued and outstanding as of the SPA Note issuance date in accordance with ASC 815. The SPA Note remained unpaid and unconverted six months following issuance and, therefore, the Contingent SPA Warrant was triggered and issued. As this was already recorded in 2015, no additional accounting was necessary upon the triggering event date.

In connection with the Company's issuance of the Initial APA Note in March 2016, the Company issued a warrant to purchase 353,540 shares of common stock in accordance with the terms of the APA (the "Initial APA Warrant") at the Exercise Price. The Initial APA Warrant has a five-year term and is exercisable commencing March 31, 2016. If the Initial APA Note was not repaid or converted on or before six months from the date of issuance, the Holder would be issued an additional warrant to purchase 353,540 shares of common stock under the same terms as the Initial APA Warrant (the "Contingent APA Warrant"). At issuance, the Company determined there was a low probability that the Initial APA Note would not be repaid or converted within the period six months from the date of issuance and, therefore, did not account for the additional warrant as issued. (The Initial APA Note was converted in April 2016.) The fair value of the warrant was calculated using the Black-Scholes option pricing model. Key valuation assumptions used consist of the Company's stock price, a risk-free interest rate of 1.42%, an expected volatility of 135%, and no expected dividends. Using an allocation of the Initial APA Note proceeds between the relative fair values of the Initial APA Warrant and the Initial APA Note, the Company recorded the Initial APA Warrant at a value of $1.7 million as additional paid-in-capital in 2016.

In connection with the Company's issuance of each of the Period Notes (see Note 8, *Hybrid Debt Instruments*) during the third quarter of 2016, the Company issued immediately exercisable warrants to purchase an aggregate of 138,381 shares of common stock at the APA Exercise Price. If the Period Notes were not repaid or converted on or before six months from the date of the respective issuances, the holders will be issued additional warrants to purchase 138,379 shares of common stock under the same terms as the immediately exercisable warrants. (The Period Notes were settled in November 2016.) The Company accounted for warrants issued in connection with the Period Notes (the "Period Warrants") as issued contemporaneous with the issuance of the associated debt instrument. The Period Warrants have five-year terms. The fair values of the Period Warrants were calculated using the Black-Scholes option pricing model. Key valuation assumptions used consist of the Company's stock price, risk free rates between 1.00% and 1.13% and expected volatilities of 110% and 120% and no expected dividends. Using allocations of the individual Period Notes proceeds between the relative fair values of the individual Period Warrants and the Period Notes, the Company recorded the Period Warrants at an aggregate value of $0.4 million as additional paid-in-capital in 2016.

In addition, warrants related to financing arrangements includes the Class A warrants to purchase 484,849 shares and the Class B warrants to purchase 1,939,393 shares issued in connection with the Company's November 7, 2016 public offering.

12. Share-Based Payments

Total share-based compensation related to stock options, RSUs, common stock awards, and non-financing warrants was approximately $1.8 million and $3.2 million for the years ended December 31, 2017 and 2016, respectively. (See Note 11, *Stockholders' Equity* for a discussion of the non-financing warrants.)

Share-based payments is classified in the consolidated statements of comprehensive loss as follows:

	Year Ended December 31,	
	2017	2016
Research and development expenses	$ 101,401	$ 1,425,995
General and administrative expenses	1,691,692	1,798,657
	$ 1,793,093	$ 3,224,652

Stock Option Modifications

During the years ended December 31, 2017 and 2016, the Company modified certain former employee stock option awards to extend the expiry dates through March 31, 2018 and 2017, respectively. As a result of the modifications, the Company recognized approximately $4,000 and $24,000 in incremental compensation expense during the years ended December 31, 2017 and 2016, respectively, which was charged to general and administrative expense in the consolidated statements of comprehensive loss.

In August 2016, the Company modified the exercise price and vesting of certain employee and non-employee stock option awards resulting in a change in incremental value and catch up of share-based amortization of approximately $0.2 million, which was charged to administrative and research and development expense.

In November 2017, the Company accelerated the vesting and extended the exercise period post termination for certain employees, including the Company's former Chief Executive Officer. These modifications resulted in a change in incremental value and catch up of share-based amortization of approximately $0.2 million, which was charged to general and administrative expense.

Stock Options

The Company grants stock option awards and RSUs to employees and non-employees with varying vesting terms under the Xenetic Biosciences, Inc. Amended and Restated Equity Incentive Plan ("Stock Plan"). The Company measures the fair value of stock option awards using the Black-Scholes option pricing model, which uses the assumptions noted in the tables below, including the risk-free interest rate, expected term, share price volatility, dividend yield and forfeiture rate. The risk-free interest rate is based upon the U.S. Treasury yield curve in effect at the time of grant, with a term that approximates the expected life of the option. For employee stock options issued in 2017 and 2016 that qualify as "plain vanilla" stock options, the expected term is based on the simplified method. The Company has a limited history of stock option exercises, which does not provide a reasonable basis for the Company to estimate the expected term of employee stock options. For all other employee stock options, the Company estimates the expected life using judgment based on the anticipated research and development milestones of the Company's clinical projects and behavior of the Company's employees. The expected life of non-employee options is the contractual life of the option. The Company determines the expected volatility based on a blended volatility rate of its own historical volatility with that of comparable publicly traded companies with drug candidates in similar therapeutic areas and stages of nonclinical and clinical development to the Company's drug candidates. The Company has applied an expected dividend yield of 0% as the Company has not historically declared a dividend and does not anticipate declaring a dividend during the expected life of the options. Further, the Company has applied a forfeiture rate of 0% as the Company has not historically experienced forfeitures. Effective January 1, 2017, the Company adopted ASU 2016-09 and elected to account for forfeitures as they occur.

Employee Stock Options

During the years ended December 31, 2017 and 2016, 700,000 and 603,622 total stock options to purchase shares of common stock were granted by the Company, respectively. The weighted average grant date fair value per option share was $2.70 and $2.94, respectively. No stock options were exercised during the years ended December 31, 2017 and 2016.

During the years ended December 31, 2017 and 2016, 340,930 and 212,472 total stock options vested, with total fair values of approximately $1.9 million and $1.7 million, respectively. As of December 31, 2017, there was approximately $2.1 million of unrecognized share-based payments related to employee stock options that are expected to vest. The Company expects to recognize this expense over a weighted-average period of approximately 1.9 years.

Key assumptions used in the Black-Scholes option pricing model for options granted to employees during the years ending December 31, 2017 and 2016 are as follows:

	Year Ended December 31,	
	2017	2016
Weighted-average expected dividend yield (%)	–	–
Weighted-average expected volatility (%)	111.37	110.11
Weighted-average risk-free interest rate (%)	1.79	1.63
Weighted-average expected life of option (years)	5.36	5.92
Weighted-average exercise price ($)	3.34	3.49

The following is a summary of employee stock option activity for the years ended December 31, 2017 and 2016:

	Number of shares	Weighted-average exercise price	Weighted-average remaining life (years)	Aggregate intrinsic value
Outstanding as of January 1, 2016	619,259	15.22	8.92	$ 1,915,942
Granted	603,622	3.49		
Expired	(29,169)	12.38		
Outstanding as of December 31, 2016	1,193,712	4.43	8.94	$ 526,073
Granted	700,000	3.34		
Expired	(113,343)	4.61		
Outstanding as of December 31, 2017	1,780,369	3.99	8.53	$ 5,273
Vested or expected to vest as of December 31, 2017	1,755,369	4.02	8.51	$ 5,273
Exercisable as of December 31, 2016	440,092	$ 5.60	8.94	$ 55,109
Exercisable as of December 31, 2017	731,895	$ 4.84	7.44	$ 5,273

A summary of the status of the Company's non-vested employee stock option shares as of December 31, 2017, and the changes during the year ended December 31, 2017, is as follows:

	Number of shares	Weighted-average grant date fair value
Balance as of January 1, 2017	753,620	$ 4.49
Granted	700,000	$ 2.70
Forfeited	(64,218)	$ 6.15
Vested	(340,928)	$ 5.87
Balance as of December 31, 2017	1,048,474	$ 2.86

Restricted Stock Units

For the year ended December 31, 2017, the Company granted 50,000 restricted stock units ("RSUs"). The RSUs vest annually over a 3-year period and had a grant date fair value of $2.11. No RSUs were vested and none expired during the year ended December 31, 2017.

Non-Employee Stock Options

Share-based payments expense related to stock options granted to non-employees is recognized as the services are rendered on a straight-line basis. The Company determined that the fair value of the stock options is more reliably measurable than the fair value of the services received. Compensation expense related to stock options granted to non-employees is subject to re-measurement at each reporting period until the options vest.

No options were granted to non-employees and none were exercised during the years ended December 31, 2017 and 2016, respectively.

During the year ended December 31, 2017 and 2016, 10,101 and 17,857 total stock options vested, with total fair values of approximately $0.1 million and $0.2 million, respectively. As of December 31, 2017, all non-employees stock options had vested. For the years ended December 31, 2017 and 2016, the Company recognized approximately $0.1 million in each period, respectively, of compensation expense related to non-employee options.

The following is a summary of non-employee stock option activity for the years ended December 31, 2017 and 2016:

	Number of shares	Weighted-average exercise price	Weighted-average remaining life (years)	Aggregate intrinsic value
Outstanding as of January 1, 2016	57,442	$ 13.39	8.23	$ 220,764
Granted	–			
Outstanding as of December 31, 2016	57,442	7.57	7.23	$ –
Granted	–			
Expired	(723)	10.34		$
Outstanding as of December 31, 2017	56,719	7.53	6.31	$ –
Vested or expected to vest as of December 31, 2017	56,719	7.53	6.31	$ –
Exercisable as of December 31, 2016	47,341	$ 8.21	6.92	$ –
Exercisable as of December 31, 2017	56,719	$ 7.53	6.31	$ –

A summary of the status of the Company's non-vested non-employee stock option shares as of December 31, 2017, and the changes during the year ended December 31, 2017 is as follows:

	Number of shares	Weighted-average grant date fair value
Balance as of January 1, 2017	10,101	$ 13.13
Vested	(10,101)	$ 13.13
Balance as of December 31, 2017	–	$ –

Common Stock Awards

The Company granted common stock awards to several non-employees in exchange for services provided. The Company measures the fair value of these awards using the fair value of the services provided or the fair value of the awards granted, whichever is more reliably measurable. The fair value measurement date of these awards is generally the date the performance of services is complete. The fair value of the awards is recognized as services are rendered on a straight-line basis. A summary of the Company's common stock awards granted and issued during the years ended December 31, 2017 and 2016 are as follows:

	Number of shares
Balance as of January 1, 2016	22,887
Granted	26,760
Issued	(19,857)
Balance as of December 31, 2016	29,790
Granted	41,800
Settled in cash	(8,773)
Balance as of December 31, 2017	62,817

The Company granted 41,800 and 26,760 shares of common stock during the years ended December 31, 2017 and 2016, respectively, in exchange for professional services. As all services were rendered in each respective period, expense related to common stock awards of approximately $0.1 million and $0.2 million was recognized during the years ended December 31, 2017 and 2016, respectively. The balance of the common stock awards has not been issued as of December 31, 2017.

Joint Share Ownership Plan

As of December 31, 2017 and 2016, there were approximately 0.3 million JSOP awards issued and outstanding to two former senior executives, respectively. Under the JSOP, shares in the Company are jointly purchased at fair market value by the participating executives and the trustees of the JSOP trust, with such shares held in the JSOP trust. For U.S. GAAP purposes the awards were valued as employee options and recorded as a reduction in equity as treasury shares until they are exercised by the employee. The JSOP awards are fully vested and have no expiration date. There were no compensation charges during the years ended December 31, 2017 and 2016, respectively.

13. Employee Benefit Plans

The Company has a defined contribution 401(k) savings plan (the "401(k) Plan"). The 401(k) Plan covers substantially all U.S. employees, and allows participants to defer a portion of their annual compensation on a pre-tax basis or make post-tax contributions. Company contributions to the 401(k) Plan may be made at the discretion of the Board of Directors. During the years ended December 31, 2017 and 2016, the Company made contributions of approximately $51,000 and $44,000, respectively, to the 401(k) Plan.

In the U.K., the Company has adopted a defined contribution plan (the "UK Plan") which qualifies under the rules established by HM Revenue & Customs. The UK Plan generally allows all U.K. employees to contribute a minimum of 3% of salary with no maximum limit. The Company contributes to the plan between 8% and 12% of the employee's salary, depending upon seniority of the employee. The Company, at its discretion, may also contribute to an employee's personal pension plan. The Company paid total contributions of approximately $0 and $48,000 during the years ended December 31, 2017 and 2016, respectively.

14. Commitments and Contingent Liabilities

Leases

In August 2013, the Company entered into an agreement to lease office and laboratory space in Lexington, Massachusetts under an operating lease with a commencement date of January 1, 2014 and a termination date of January 31, 2019. With the execution of this lease, the Company is required to maintain a $66,000 letter of credit as a security deposit, which is classified as a current asset within the consolidated balance sheets. In connection with the Lexington lease, the Company has approximately $32,000 recorded as prepaid rent as of December 31, 2017, with approximately $2,000 recorded as a non-current asset. The Company also incurred a liability of $89,074 with respect to the Company's contribution to the landlord's leasehold improvements, of which approximately $20,000 is outstanding and reflected as a current liability as of December 31, 2017. This liability is repayable as additional rent expense over the term of the lease and bears interest at 6%.

In December 2016, the Company entered into a one-year lease of office space in Miami, Florida, under an operating lease with a commencement date of December 1, 2016, and a termination date of November 30, 2017. The Company renewed this lease in November 2017 for an additional two years with a revised termination date of November 30, 2019.

The Company's contractual commitments under all non-cancelable operating leases as of December 31, 2017, are as follows:

As of December 31,	Total Operating Leases
2018	$ 123,663
2019	24,583
2020	–
Total minimum lease payments	$ 148,246

Rent expense is calculated on a straight-line basis over the term of the leases. Rent expense under the Company's operating leases was approximately $0.1 million for the years ended December 31, 2017 and 2016, respectively.

Litigation

On August 27, 2015, Eurogentec S.A. ("EGT"), a former supplier of the Company, brought an action against the Company in the Commercial Court of the Canton of Zurich Switzerland (the "Court") alleging nonpayment of invoices for services provided by EGT. The Company requested dismissal of the claim based on the argument that EGT knew, or should have known, that the services provided by EGT should not have been performed or had not been properly performed. On July 12, 2017, the Court rendered a decision in favor of EGT ordering the Company to pay approximately $0.7 million to EGT, representing all amounts that EGT alleged were owed by the Company, plus interest and court and legal fees. The Company had previously recorded $0.6 million related to this contract when the relevant services were provided and accrued an additional $0.1 million related to interest and fees in 2017 as a result of the ruling. In December 2017, the Company entered into a Settlement Agreement and paid approximately $0.6 million to settle all claims associated with this matter.

15. Related Party Transactions

In May 2011, the Company received a short term unsecured loan facility of up to $1.7 million from SynBio (the "SynBio Loan"), an affiliate of the Company. In connection with the APA, the Company made a series of payments during the first two quarters of 2016 totaling approximately $0.3 million to creditors of Kevelt. Pursuant to the APA, such payments are considered direct offsets to the loan with SynBio.

In December 2016, the Company entered into an agreement with SynBio, Pharmsynthez, and Kevelt which settled all amounts owed on the SynBio Loan, Kevelt services provided to Xenetic in connection with the XBIO-101 Phase 2 project, and the purchase of drug candidate supply from Kevelt sufficient to meet the needs of the XBIO-101 Phase 2 clinical trial. Pursuant to this agreement, the Company transferred approximately $0.6 million to the counter parties. No amounts were outstanding under the SynBio Loan as of December 31, 2017 and 2016, respectively.

The Company has entered into various research, development, license and supply agreements with Shire, SynBio, Serum Institute and Pharmsynthez, each a related party whose relationship, ownership, and nature of transactions is disclosed within other sections of these footnotes.

During the years ended December 31, 2017 and 2016, the Company received research and consulting services from a director of Pharmsynthez, a controlling stockholder of the Company. The total amount of services received was approximately $0.1 million for the years ended December 31, 2017 and 2016, respectively. This consulting agreement was terminated in July 2017.

Please refer to Note 4, *Significant Strategic Drug Development Collaborations – Related Parties,* Note 8, *Hybrid Debt Instruments*, and Note 11, *Stockholder's Equity*, for details on arrangements with collaboration partners and non-employee directors that are also related parties.

16. Subsequent Events

The Company performed a review of events subsequent to the balance sheet date through the date the financial statements were issued and determined that there were no such events requiring recognition or disclosure in the financial statements.

XENETIC BIOSCIENCES, INC.

SCHEDULE II

VALUATION AND QUALIFYING ACCOUNTS

FOR THE YEARS ENDED DECEMBER 31, 2017 AND 2016

Valuation Allowance on Deferred Tax Assets	Balance Beginning of Period	Additions (Deductions) Charged to (from) Income Tax Expense	Other Changes to Valuation Allowance	Balance End of Period
2017	$ (21,503,782)	(1,261,157)	–	$ (22,764,939)
2016	$ (15,324,438)	(6,179,344)	–	$ (21,503,782)

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

Not applicable.

ITEM 9A – CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), as of the end of the period covered by this Annual Report on Form 10-K.

Based on this evaluation our management, including our Chief Executive Officer and Chief Financial Officer, concluded that, as of December 31, 2017, our disclosure controls and procedures are designed at a reasonable assurance level and are effective to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate, to allow timely decisions regarding required disclosure.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) of the Exchange Act. Management, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, conducted an assessment of the design and effectiveness of our internal control over financial reporting as of the end of the period covered by this Annual Report on Form 10-K. In making its assessment of internal control over financial reporting, management used the criteria set forth by the Committee of Sponsoring Organizations ("COSO") of the Treadway Commission in *Internal Control — Integrated Framework (2013 Framework)*. Based on this assessment, our management concluded that, as of the end of the period covered by this Annual Report on Form 10-K, our internal control over financial reporting was effective based on the criteria set forth by COSO of the Treadway Commission in *Internal Control — Integrated Framework*.

This annual report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our registered public accounting firm pursuant to an exemption for non-accelerated filers set forth in Section 989G of the Dodd-Frank Wall Street Reform and Consumer Protection Act.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting that occurred during the period covered by this Annual Report on Form 10-K that have materially affected, or are 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. The Company's internal control over financial reporting includes those policies and procedures that:

(1) Pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the Company's assets;
(2) Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that the Company's receipts and expenditures are being made only in accordance with authorizations of the Company's management and directors; and
(3) Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the Company's assets that could have a material effect on the financial statements.

Management, including the Company's principal executive and principal financial officers, or persons performing similar functions, does not expect that the Company's internal controls will prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of internal controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. Also, any evaluation of the effectiveness of controls in future periods are subject to the risk that those internal controls may become inadequate because of changes in business conditions, or that the degree of compliance with the policies or procedures may deteriorate.

ITEM 9B – OTHER INFORMATION

None.

PART III

ITEM 10 – DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this Item will be set forth in the Company's definitive proxy statement or information statement to be filed with the SEC in connection with the Company's 2018 Annual Meeting of Stockholders within 120 days of the end of the Company's fiscal year ended December 31, 2017 and is incorporated herein by reference.

ITEM 11 – EXECUTIVE COMPENSATION

The information required by this Item will be set forth in the Company's definitive proxy statement or information statement to be filed with the SEC in connection with the Company's 2018 Annual Meeting of Stockholders within 120 days of the end of the Company's fiscal year ended December 31, 2017 and is incorporated herein by reference.

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

The information required by this Item will be set forth in the Company's definitive proxy statement or information statement to be filed with the SEC in connection with the Company's 2018 Annual Meeting of Stockholders within 120 days of the end of the Company's fiscal year ended December 31, 2017 and is incorporated herein by reference.

ITEM 13 – CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this Item will be set forth in the Company's definitive proxy statement or information statement to be filed with the SEC in connection with the Company's 2018 Annual Meeting of Stockholders within 120 days of the end of the Company's fiscal year ended December 31, 2017 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 Company's definitive proxy statement or information statement to be filed with the SEC in connection with the Company's 2018 Annual Meeting of Stockholders within 120 days of the end of the Company's fiscal year ended December 31, 2017 and is incorporated herein by reference.

PART IV

ITEM 15 – EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) The following is filed as part of this Annual Report on Form 10-K:

- *Consolidated Financial Statements:* The consolidated financial statements and report of independent registered public accounting firm required by this item are included in Part II, Item 8;
- *Financial Statement Schedules:* Schedule II, Valuation and Qualifying Accounts, is included in Part II, Item 8.

All other schedules are omitted because they are not applicable or not required, or because the required information is shown either in the consolidated financial statements or in the notes thereto.

(b) **Exhibits:** The exhibits which are filed or furnished with this Annual Report on Form 10-K or which are incorporated herein by reference are set forth in the Exhibit Index beginning on page 60 which is incorporated herein by reference.

ITEM 16 – FORM 10-K SUMMARY

Not applicable.

EXHIBIT INDEX

Exhibit No.	Exhibit Index	Form	Filing Date	Exhibit Number	Filed Herewith
2.1	Scheme of Arrangement (court order)	8-K	01/29/2014	2.1	
3.1	Articles of Incorporation	S-1	11/21/2011	3.1	
3.2	Certificate of Amendment to Articles of Incorporation	8-K	02/12/2013	3.1	
3.3	Certificate of Amendment to Articles of Incorporation	8-K	02/27/2013	3.1	
3.4	Certificate of Amendment to Articles of Incorporation	10-Q	01/10/2014	3.1	
3.5	Certificate of Change Pursuant to NRS 78.209	10-Q	01/10/2014	3.2	
3.6	Certificate of Amendment to Articles of Incorporation	8-K	09/30/2015	3.1	
3.7	Amended and Restated Bylaws	8-K	02/27/2017	3.1	
3.8	Form of Amended and Restated Certificate of Designation of Preferences, Rights and Limitations of Series A Preferred Stock	S-1/A	10/27/2016	3.8	
3.9	Second Amended and Restated Certificate of Designation of Preferences, Rights and Limitations of Series B Preferred Stock	S-1/A	10/31/2016	3.9	
4.1	Form of Common Stock Certificate of the Registrant	S-1/A	07/14/2016	4.1	
4.2	Xenetic Biosciences, Inc. Shareholder Voting Agreement dated October 26, 2016 between Xenetic Biosciences Inc. and SynBio, LLC	S-1/A	10/27/2016	4.2	
4.3	SynBio LLC Warrant to Purchase Common Stock of Xenetic Bioscience, Incorporated	10-K	04/15/2015	10.2	
4.4	Serum Institute of India Limited Warrant to Purchase Common Stock of Xenetic Bioscience, Incorporated	10-K	04/15/2015	10.03	
4.5	Firdaus Jal Dastoor Warrant to Purchase Common Stock of Xenetic Bioscience, Incorporated	10-K	04/15/2015	10.04	
4.6	Form of Common Stock Purchase Warrant	8-K	11/16/2015	10.3	
4.7	Form of Common Stock Purchase Warrant	8-K	11/16/2015	10.4	
4.8	Form of Amended and Restated Common Stock Purchase Warrant	8-K	11/16/2015	10.6	
4.9	Form of Common Stock Purchase Warrant	8-K	07/08/2016	10.3	
4.10	Form of Common Stock Purchase Warrant	S-1/A	10/31/2016	10.53	
4.11	Form of Ten Percent (10%) Senior Secured Convertible Promissory Note	8-K	11/16/2015	10.2	
4.12	Form of Ten Percent (10%) Junior Secured Convertible Promissory Note – Due Deferral End Date	8-K	07/08/2016	10.2	
4.13	Form of Amended and Restated Ten Percent (10%) Senior Secured Convertible Promissory Note	8-K	11/16/2015	10.5	
4.14	Registration Rights Agreement, dated July 1, 2015, between Xenetic Bioscience, Inc. and OJSC Pharmsynthez	8-K	07/08/2015	10.3	
4.15	Form of First Amendment to Registration Rights Agreement	8-K	11/16/2015	10.8	
10.1	Possible Offer for Xenetic Biosciences plc by General Sales & Leasing, Inc., dated October 21, 2013	8-K	10/21/2013	9.1	
10.2	Recommended Acquisition of Xenetic Biosciences plc by General Sales & Leasing, Inc. including Scheme of Arrangement	8-K/A	11/25/2013	9.1	
10.3	Announcement of Recommended Offer by General Sales and Leasing, Inc. for shares of Xenetic Biosciences plc, dated November 12, 2013	8-K	11/25/2013	9.2	
10.4	Agreement of Conveyance, Transfer and Assignment of Subsidiaries and Assumption of Obligations dated November 12, 2013 between General Sales Inc., Leasing, Inc., Oxbridge Technology Partners, SA, Shift It Media Company and General Aircraft, Inc.	10-K	11/27/2013	9.3	
10.5†	Form of Rules of the Lipoxen plc Unapproved Share Option Plan dated July 18, 2000 (as amended by a resolution of the board of directors of Lipoxen plc passed on March 14, 2006)	10-K	04/15/2014	10.5	
10.6†	Form of Xenetic Biosciences plc 2007 Share Option Scheme and US Addendum (as established in 2007 and by resolution of shareholders in 2010 and awarded by board resolution in 2012)	10-K	04/15/2014	10.6	

Exhibit No.	Exhibit Index	Form	Filing Date	Exhibit Number	Filed Herewith
10.7†	Form of Amended and Restated Xenetic Biosciences, Inc. Equity Incentive Plan, effective November 15, 2017	DEFR14A	11/03/2017	Appendix A	
10.8	Master Clinical Research Services Agreement between Novotech Pty Limited and Xenetic Biosciences plc dated Feb. 6, 2013	10-K	04/15/2014	10.17	
10.9†#	Employment Agreement, dated November 3, 2009, between Lipoxen plc and M. Scott Maguire	10-K/A	02/18/2015	10.01	
10.10	Form of Lease for Ledgemont Research Center, Lexington, Massachusetts dated August 1, 2013 between One Ledgemont LLC and Xenetic Bioscience, Inc.	10-K/A	02/18/2015	10.03	
10.11	Stock Purchase Agreement, dated January 29, 2014, between Xenetic Biosciences, Inc. and Baxter Healthcare SA	10-K/A	02/18/2015	10.08	
10.12	Stock Purchase Agreement Amendment No. 1, dated February 14, 2014, between Xenetic Biosciences, Inc. and Baxter Healthcare SA	10-K/A	02/18/2015	10.09	
10.13#	Exclusive Research, Development and License Agreement, dated August 15, 2005, between Lipoxen Technologies Limited, Baxter Healthcare SA and Baxter Healthcare Corporation	10-K/A	02/18/2015	10.10	
10.14#	Letter Agreement, dated December 11, 2006, between Lipoxen Technologies Limited, Baxter Healthcare SA, Baxter Healthcare Corporation and Serum Institute of India Limited	10-K/A	02/18/2015	10.11	
10.15#	Amendment to the Exclusive Research, Development and License Agreement, dated December 13, 2006, between Lipoxen Technologies Limited, Baxter Healthcare SA and Baxter Healthcare Corporation	10-K/A	02/18/2015	10.12	
10.16#	Second Amendment to the Exclusive Research, Development and License Agreement, dated May 28, 2009, between Lipoxen Technologies Limited, Baxter Healthcare SA and Baxter Healthcare Corporation	10-K/A	02/18/2015	10.13	
10.17#	Amendment Number Four to the Exclusive Research, Development and License Agreement, dated August 10, 2010, between Lipoxen Technologies Ltd., Baxter Healthcare SA and Baxter Healthcare Corporation	10-K/A	02/18/2015	10.14	
10.18#	Amendment Number Five to the Exclusive Research, Development and License Agreement, dated September 15, 2010, between Lipoxen Technologies Ltd., Baxter Healthcare SA and Baxter Healthcare Corporation	10-K/A	02/18/2015	10.15	
10.19#	Form of Sixth Amendment to the Exclusive Research, Development and License Agreement, dated January 29, 2014, between Lipoxen Technologies Limited, Baxter Healthcare SA and Baxter Healthcare Corporation	10-K/A	02/18/2015	10.16	
10.20#	Agreement on Co-Development and the Terms of Exclusive License dated August 4, 2011 between Lipoxen plc, Lipoxen Technologies LTD and SynBio LLC	10-K/A	02/18/2015	10.18	
10.21#	Subscription Agreement in respect of ordinary shares in the capital of Lipoxen plc dated August 4, 2011 between SynBio LLC and Lipoxen plc	10-K/A	02/18/2015	10.19	
10.22#	Collaboration, License and Development Agreement, dated November 11, 2009, between Pharmsynthez ZAO and Lipoxen Technologies Ltd.	10-K/A	02/18/2015	10.20	
10.23#	Exclusive Patent and Know How License and Manufacturing Agreement, dated August 4, 2011, between Lipoxen plc, Lipoxen Technologies Ltd and Serum Institute of India Limited	10-K/A	02/18/2015	10.21	
10.24†	Employment Agreement, dated April 30, 2012, between Xenetic Bioscience, Inc. and Dr. Henry Hoppe IV.	10-K/A	02/18/2015	10.23	
10.25	Intellectual Property Assignment between Dmitry Genkin, FDS Pharma, Lipoxen Technologies Limited and Xenetic Biosciences Inc.	10-K	04/15/2015	10.1	
10.26	Securities Purchase Agreement, dated May 2015, between Xenetic Bioscience, Inc. and OJSC Pharmsynthez	8-K	07/08/2015	10.1	

Exhibit No.	Exhibit Index	Form	Filing Date	Exhibit Number	Filed Herewith
10.27	Security Agreement dated July 1, 2015, between Xenetic Bioscience, Inc. and OJSC Pharmsynthez	8-K	07/08/2015	10.4	
10.28	Subsidiary Guarantee dated July 1, 2015, between Xenetic Bioscience, Inc. and OJSC Pharmsynthez	8-K	07/08/2015	10.5	
10.29	Form of Assignment and Assumption Agreement	8-K	07/08/2015	10.7	
10.30#	Settlement Agreement, dated August 27, 2015, between Xenetic Biosciences (UK) Limited, Xenetic Biosciences, Inc., Lipoxen Technologies Limited and Colin Hill	8-K	09/02/2015	10.1	
10.31	Form of Asset Purchase Agreement, dated as of November 13, 2015, by and among Xenetic Biosciences, Inc., Lipoxen Technologies, LTD, a U.K. corporation, AS Kevelt, an Estonian company and OJSC Pharmsynthez	8-K	11/16/2015	10.1	
10.32	Form of First Amendment to Securities Purchase Agreement	8-K	11/16/2015	10.7	
10.33	Form of First Amendment to Security Agreement	8-K	11/16/2015	10.9	
10.34	Form of First Amendment to Subsidiary Guarantee	8-K	11/16/2015	10.10	
10.35	Form of Transition, Services and Resupply Agreement by and among Xenetic Bioscience, Inc., AS Kevelt and OJSC Pharmsynthez	8-K	11/16/2015	10.11	
10.36†	Letter Agreement re. Appointment of Non – Employee, Independent Director of Xenetic Biosciences, Inc. for Roger D. Kornberg dated February 2016	8-K	02/29/2016	10.1	
10.37†	Deferred Salary Security Agreement, dated July 1, 2016 between Xenetic Bioscience, Inc. and M. Scott Maguire	8-K	07/08/2016	10.1	
10.38†	Letter Agreement re. Appointment of Non – Employee, Independent Director of Xenetic Biosciences, Inc. for Jeffrey F. Eisenberg dated July 8, 2016	8-K	07/12/2016	10.1	
10.39†	Letter Agreement re. Appointment of Non – Employee, Independent Director of Xenetic Biosciences, Inc. for Dr. Edward J. Benz dated November 18, 2016	8-K	11/22/2016	10.1	
10.40†	Employment Agreement, dated December 1, 2016, between Xenetic Biosciences, Inc. and Jeffrey Eisenberg	8-K	12/6/2016	10.1	
10.41†	Employment Agreement, dated January 1, 2017 between Xenetic Biosciences, Inc. and Curtis Lockshin	8-K	01/04/2017	10.1	
10.42†	Employment Agreement, dated March 23, 2017 between Xenetic Biosciences, Inc. and James F. Parslow	8-K	04/04/2017	10.1	
10.43†	Inducement Award Agreement, dated April 3, 2017, between Xenetic Biosciences, Inc. and James F. Parslow	8-K	04/04/2017	10.2	
10.44†	Form of Indemnity Agreement by and between Xenetic Biosciences, Inc. and each of its directors and executive officers	10-Q	08/14/2017	10.1	
10.45†	Amended and Restated Employment Agreement, dated October 26, 2017, between Xenetic Biosciences, Inc. and Jeffrey Eisenberg				X
10.46#	Right to Sublicense Agreement, dated October 27, 2017, by and among Xenetic Biosciences, Inc., Baxalta Incorporated, Baxalta US Inc., and Baxalta GmbH				X
10.47†	Settlement Agreement, dated November 3, 2017, by and among M. Scott Maguire, Xenetic Biosciences (UK) Limited and Lipoxen Technologies, Limited				X
10.48†	Letter Agreement re. Appointment of Non – Employee, Independent Director of Xenetic Biosciences, Inc. for Adam Logal dated October 11, 2017				X
10.49†	Letter Agreement re. Appointment of Non – Employee, Independent Director of Xenetic Biosciences, Inc. for James E. Callaway dated October 11, 2017				X
21.1	List of Subsidiaries				X
23.1	Consent of Marcum LLP				X
24.1	Power of Attorney (included on signature page)				X
31.1	Certification of Principal Executive Officer, as required by Rule 13a-14(a) or Rule 15d-14(a)				X
31.2	Certification of Principal Financial Officer, as required by Rule 13a-14(a) or Rule 15d-14(a)				X
32.1*	Certification of Principal Executive Officer and Principal Financial Officer, as required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 36 of Title 18 of the United States Code (18 U.S.C. §1350)				X
101.INS	XBRL Instance Document.				X
101.SCH	XBRL Taxonomy Extension Schema Document.				X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.				X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.				X

101.LAB	XBRL Taxonomy Extension Label Linkbase Document.	X
101.PRE	XRBL Taxonomy Extension Presentation Linkbase Document.	X

† Indicates a management contract or any compensatory plan, contract or arrangement.

Application has been made with the Securities and Exchange Commission to seek confidential treatment of certain confidential material contained in this document. Omitted material for which confidential treatment has been requested has been filed separately with the Securities and Exchange Commission.

* This certification is deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended.

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.

XENETIC BIOSCIENCES, INC.

Date: March 30, 2018 By: /s/ JEFFREY F. EISENBERG
Jeffrey F. Eisenberg
Chief Executive Officer

POWER OF ATTORNEY AND SIGNATURES

We, the undersigned officers and directors of Xenetic Biosciences, Inc., hereby severally constitute and appoint Jeffrey F. Eisenberg, our true and lawful attorney, with full power to him, to sign for us in our names in the capacities indicated below, all amendments to this report, and generally to do all things in our names and on our behalf in such capacities to enable Xenetic Biosciences, Inc. to comply with the provisions of the Securities Exchange Act of 1934, as amended, and all requirements of the Securities and Exchange Commission.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities indicated below on the 30th day of March, 2018.

Signature	**Title(s)**
/s/ JEFFREY F. EISENBERG Jeffrey F. Eisenberg	Chief Executive Officer and Director (*Principal Executive Officer)*
/s/ JAMES PARSLOW James Parslow	Chief Financial Officer *(Principal Financial Officer and Principal Accounting Officer*)
/s/ JAMES CALLAWAY James Callaway	Director
/s/ FIRDAUS JAL DASTOOR FCS Firdaus Jal Dastoor FCS	Director
/s/ DMITRY GENKIN Dmitry Genkin	Director
/s/ ROMAN KNYAZEV Roman Knyazev	Director
/s/ ROGER KORNBERG Roger Kornberg	Director
/s/ ADAM LOGAL Adam Logal	Director

Exhibit 10.45

XENETIC BIOSCIENCES INC.

AMENDED AND RESTATED EMPLOYMENT AGREEMENT

This Amended and Restated Employment Agreement ("Agreement") is entered into as of this 26th day of October, 2017 by and between Xenetic Biosciences, Inc., a Nevada corporation with a principal place of business in Lexington, Massachusetts (the "Company"), and Jeffrey Eisenberg, an individual (the "Executive").

WHEREAS, the Company and Executive previously entered into an employment agreement on December 1, 2016 to employ Executive as the Chief Operating Officer of the Company (the "Prior Agreement");

WHEREAS, the Company and Executive desire to amend and restate the Prior Agreement in its entirety to employ Executive as the Chief Executive Officer of the Company on the terms and conditions contained in this Agreement.

WHEREAS, the Company and the Executive wish to set forth the terms and conditions for the employment of the Executive by the Company;

NOW THEREFORE, in consideration of the mutual covenants and agreements contained herein, and other good and valuable consideration the receipt of which is hereby acknowledged, the Company and the Executive hereby agree to amend and restate the Prior Agreement and the parties mutually agree as follows:

Section 1. Term of Employment.

(a) General. The Company will employ Executive, and Executive will be employed by the Company, for the period set forth in Section 1(b), in the positions set forth in Section 2, and upon the other terms and conditions herein provided commencing on October 26, 2017 (the "Effective Date").

(b) Term. The initial term of employment under this Agreement (the "Initial Term") shall be for the period beginning on the Effective Date and ending on the first anniversary thereof, unless earlier terminated as provided in Section 7. The Initial Term shall automatically be extended for successive one year periods (each, an "Extension Term" and, collectively with the Initial Term, the "Term"), unless either party hereto gives notice of non-extension to the other no later than 90 days prior to the expiration of the then-applicable Term. The Executive's employment with the Company shall be "at will," meaning that the Executive's employment may be terminated by the Company or the Executive at any time and for any reason.

(c) Location. During the Term, the Executive's principal place of employment shall be in Miami, Florida or Lexington, MA, at the discretion of the Executive. The Executive acknowledges that Executive's duties and responsibilities shall require the Executive to travel on business to the extent reasonably necessary to fully perform Executive's duties and responsibilities hereunder.

Section 2. Duties and Exclusivity.

(a) During the Term, the Executive (i) shall serve as Chief Executive Officer of the Company, with responsibilities, duties and authority customary for such position, subject to direction by the Board of Directors of the Company (the "Board"), (ii) shall report directly to the Board; (iii) shall devote substantially all the Executive's working time and efforts to the business and affairs of the Company and its subsidiaries; and (iv) agrees to observe and comply with the Company's rules and policies as adopted by the Company from time to time. The Executive's duties, responsibilities and authority may include services for one or more subsidiaries of the Company.

(b) Notwithstanding anything to the contrary in Section 2(a) above, the Executive may (i) serve as a director, trustee or officer or otherwise participate in not-for-profit educational, welfare, social, religious and civic organizations; and (ii) with the advanced consent of the Board, serve on the board of directors of other companies, to the extent that such other activities, either individually or in the aggregate, do not inhibit or interfere with the performance of the Executive's duties under this Agreement. By approving this Agreement, the Board consents to the Executive's service as a director at Mabvax Therapeutics, Inc.

(c) Board Membership. Executive shall serve as a member of the Board until the term of his directorship expires and he is not re-elected or his earlier resignation or removal from the Board. During the Term, the Nominating and Corporate Governance Committee will recommend the Executive for reelection to the Board. Executive's service as a Board member shall be without further cash compensation. At the request of the Board, Executive shall resign from the Board and any committees thereof effective immediately upon the termination of Executive's employment with the Company for any reason and, in the absence of any other written resignation proffered to the Board, this Agreement shall constitute such a written resignation.

(d) Exclusivity. The Executive hereby represents to the Company that: (i) the execution and delivery of this Agreement by the Executive and the Company and the performance by the Executive of the Executive's duties hereunder do not and shall not constitute a breach of, conflict with, or otherwise contravene or cause a default under, the terms of any other agreement or policy to which the Executive is a party or otherwise bound or any judgment, order or decree to which the Executive is subject; (ii) that the Executive has no information (including, without limitation, confidential information and trade secrets) relating to any other Person which would prevent, or be violated by, the Executive entering into this Agreement or carrying out his duties hereunder; (iii) the Executive is not bound by any agreement with any previous employer or other party to refrain from (A) competing with the business of, or (B) soliciting the customers of, that employer or party, in each case, which would be violated by your employment with the Company; and (iv) the Executive understands the Company will rely upon the accuracy and truth of the representations and warranties of the Executive set forth herein and the Executive consents to such reliance.

(e) Deemed Resignation. Upon termination of Executive's employment for any reason, Executive shall be deemed to have resigned from all offices, if any, then held with the Company or any of its subsidiaries, and, at the Company's request, Executive shall execute such documents as are necessary or desirable to effectuate such resignations.

Section 3. Compensation.

(a) Salary. In consideration of all of the services rendered by the Executive under the terms of this Agreement, the Company shall pay to the Executive a base salary at the annualized rate of Three Hundred Thousand Dollars United States ($300,000.00) per annum, less payroll deductions and all required withholdings. Executive's Base Salary shall be subject to annual review and upward adjustment only by the Board or a committee thereof, beginning in fiscal 2018. The Base Salary shall be paid in accordance with the customary payroll practices of the Company in effect from time to time. The Executive's salary, as adjusted from time to time under this Section 3(a), is referred to as ("Base Salary").

(b) Annual Bonus. With respect to each Company fiscal year that ends during the Term, commencing with fiscal year 2017, the Executive shall be eligible to receive an annual performance-based cash bonus (the "Annual Bonus") which shall be payable based upon the attainment of individual and/or Company performance goals established by the Board or a committee thereof. The target amount of such Annual Bonus shall equal 50% of Executive's Base Salary in the year to which the Annual Bonus relates, provided that the actual amount of the Annual Bonus may be greater or less than such target amount (the "Target Bonus"). Each Annual Bonus, if any, for a fiscal year shall be payable, less payroll deductions and all required withholdings, not later than the fifteenth day of the third month following the end of such year. Except as provided in Section 7, notwithstanding any other provision of this Section 3(b), no bonus shall be payable with respect to a Company fiscal year unless the Executive remains continuously employed with the Company until the last day of such year.

(c) Reimbursement of Expenses. The Company will promptly reimburse Executive for all reasonable out-of-pocket business expenses that are incurred by Executive in furtherance of the Company's business in accordance with the Company's policies with respect thereto as in effect from time to time. Without limiting the foregoing, the Company shall reimburse the Executive for the Executive's reasonable travel and lodging expenses in connection with the Executive's travel for business purposes between his primary residence in Miami-Dade County, Florida and Lexington, Massachusetts or other business locations of the Company and its subsidiaries and the Company shall withhold from such payment all amounts required to be deducted or withheld under applicable law. The Executive shall be reimbursed by the Company for the reasonable attorneys' fees and costs incurred by him in connection with the negotiation and preparation of this Agreement (and related equity award documentation), up to a maximum of $5,000 provided that the Executive shall submit invoices to the Company within ninety (90) days of incurrence of the expense, and the Company shall reimburse Executive within sixty (60) days thereafter.

(d) Fringe Benefits. In addition to any benefits provided by this Agreement, Executive shall be entitled to participate generally in all employee benefit, welfare and other plans, practices, policies and programs and fringe benefits maintained by the Company from time to time on a basis no less favorable than those provided to other similarly-situated executives of the Company. The Executive understands that, except when prohibited by applicable law, the Company's benefit plans and fringe benefits may be amended, enlarged, diminished or terminated prospectively by the Company from time to time, in its sole discretion, and that such shall not be deemed to be a breach of this Agreement. Regardless of where the Executive is based, the Company shall procure and pay for a comprehensive health check for the Executive once per year during the Term, until the termination of the Executive's employment, to be carried out by a medical professional agreeable to the Executive (acting reasonably).

(e) Vacation. Executive shall be entitled to accrue four (4) weeks of paid vacation days per year in accordance with and subject to the terms of the Company's vacation policy applicable to other executive officers of the Company, as it may be amended prospectively from time to time.

Section 4. Insurance; Indemnification.

During Executive's employment with the Company, the Company shall maintain the insurance it currently has with respect to (i) directors' and officers' liability, (ii) errors and omissions and (iii) general liability insurance providing coverage to Executive to the same extent as other senior executives and directors of the Company. Executive's coverage under such insurance shall terminate upon Executive's leaving of the Company's employ for any reason. The Executive will be entitled to indemnification with respect to Executive's services provided hereunder pursuant to Nevada law, the terms and conditions of Company's articles of incorporation and/or bylaws, Company's directors and officers ("D&O") liability insurance policy, and Company's standard indemnification agreement for directors and officers as executed by Company and Executive.

Section 5. Equity Awards.

(a) Restricted Stock Unit Grant. The Company shall grant to the Executive on the Effective Date restricted stock units (the "RSUs") under the Company's Amended and Restated Xenetic Biosciences, Inc. Equity Incentive Plan, adopted by the Board of Directors on October 11, 2017, as amended from time to time (the "Plan") for 50,000 shares of the Company's common stock. The RSUs shall vest one-third upon the first anniversary of the Effective Date, one-third upon the second anniversary of the Effective Date and one-third upon the third anniversary of the Effective Date, provided the Executive remains employed with the Company on the applicable vesting date and further provided that, in the event of (i) a Change in Control, as defined in the Plan, while Executive is employed by the Company, any unvested portion of the RSUs shall vest immediately upon the Change in Control, or (ii) a termination of this Agreement by the Company under Section 7(b) or the Executive under Section 7(c), any unvested portion of the RSUs shall vest immediately upon such termination. The RSUs (including the distribution of any shares of the Company's common stock issuable pursuant thereto) shall be subject to the terms of the Plan, and a Restricted Stock Unit Agreement in a form acceptable to the Committee, which shall include the terms provided herein. The Company represents and warrants to the Executive that (i) this Agreement and the RSUs have been duly authorized by the Company's Compensation Committee of the Company's Board of Directors (the "Compensation Committee") and are the valid and binding obligations of the Company, enforceable in accordance with their respective terms; and (ii) the grant of the RSUs does not violate applicable law or Nasdaq listing requirements.

(b) Delivery of Shares. The Restricted Stock Unit Agreement described in Section 5(a) shall require the Company to deliver shares of Company's Common Stock (as defined in the Plan) in satisfaction of the vested RSUs granted under such Agreement to the Participant or direct its transfer agent to register such shares in book entry form, upon, but in no event later than thirty (30) days following, the earlier of: (i) Participant's "separation from service" as defined for purposes of Code Section 409A (as defined below), or (ii) a Change in Control that constitues a change in the ownership of, effective control of, or a change in the ownership of a substantial portion of the assets of, the Company within the meaning of Code Section 409A (collectively, the "Delivery Event"); provided, however, that the delivery of shares shall be delayed until the earlier of (A) six months following separation from service, or (B) the Participant's death, if necessary to comply with the requirements of Code Section 409A. All shares underlying vested Restricted Stock Units shall be delivered to Participant upon a Delivery Event regardless as to the reason triggering such Delivery Event (including the reason the Participant's service is terminated).

(c) Stock Option Grant. The Company shall grant to Executive on the Effective Date a stock option to purchase 250,000 shares of common stock of the Company (the "Option") under the Plan at an exercise price equal to the fair market value of the Company's common stock on the grant date. Fifty percent of the Option shall vest one-third upon the first anniversary of the Effective Date, one-third upon the second anniversary of the Effective Date and one-third upon the third anniversary of the Effective Date, a portion of the Option to purchase 100,000 shares of common stock of the Company shall vest upon the achievement of key clinical milestones for XBIO-101 as further described in the Option award agreements, and a portion of the Option to purchase 25,000 shares of common stock of the Company shall vest upon the achievement of key development milestones related to PSA as further described in the Option award agreements, provided the Executive remains employed with the Company on the applicable vesting date and further provided that, in the event of (i) a Change in Control, as defined in the Plan, while Executive is employed by the Company, any unvested portion of the Option shall vest immediately upon the Change in Control, or (ii) a termination of this Agreement by the Company under Section 7(b) or the Executive under Section 7(c), any unvested portion of the Option shall vest immediately upon such termination. Notwithstanding the foregoing in no event may (i) Executive exercise the Option prior to the Company receiving shareholder approval of an increase in the number of shares of common stock authorized under the Plan which amendment to the Plan shall include provision for the issuance of shares of common stock underlying the Option; and (ii) if shareholder approval is not obtained for any reason on or prior to October 11, 2018, the Option shall be cancelled and of no further force and effect. A cancellation of the Option shall in no event be deemed a breach of this Agreement. The Option shall be evidenced in writing by, and subject to the terms and conditions of, the Plan or such new plan covering the Option with terms that are the same as or materially similar to the terms of the Plan and, except as otherwise set forth herein, the Company's standard form of stock option agreement, which agreement shall expire ten (10) years from the date of grant except as otherwise provided herein, in the stock option agreement or the Plan. The Executive shall be eligible to receive from time to time additional equity awards under the Plan. The Company represents and warrants to the Executive that (i) this Agreement and the Option have been duly authorized by the Company's Board of Directors or a committee thereof and are the valid and binding obligations of the Company, enforceable in accordance with their respective terms, including the Company's right to terminate the Option if no stockholder consent is obtained in a timely manner; and (ii) the grant of the Option does not violate applicable law or Nasdaq listing requirements.

(d) Extension of Exercise Period. Except with respect to the Incentive Stock Option granted to the Executive on December 2, 2016, all options previously granted to Executive are hereby amended to, and all options granted in the future shall allow Executive upon termination of employment for any reason other than Cause to exercise the vested stock options for a period of the lesser of twelve months following termination or the 10 year expiration date set forth in the option agreement.

(e) Sale of Shares. Executive agrees that he will not loan or pledge any securities of the Company owned by him or which he may accrue in the future through Options or other equity awards as collateral for any indebtedness except with the Committee's approval.

Section 6. Compliance with Company Policy.

During the Term, the Executive shall observe all Company rules, regulations, policies, procedures and practices in effect from time to time, including, without limitation, such policies and procedures as are contained in the Company policy and procedures manual, as may be amended or superseded from time to time.

Section 7. Termination of Employment.

Executive's employment with the Company may be terminated during Term of this Agreement for any of the following reasons:

(a) By The Company For Cause. At any time during the Term, the Company may terminate Executive's employment hereunder for Cause. For purposes of this Agreement, "Cause" shall mean the occurrence of any of the following events: (i) conduct by Executive constituting a material act of willful misconduct in connection with the performance of his duties, including, without limitation, misappropriation of funds or property of the Company or any of its affiliates other than the occasional, customary and *de minimis* use of Company property for personal purposes; (ii) the commission by Executive of a felony or any misdemeanor involving moral turpitude, deceit, dishonesty or fraud, or conduct by Executive that would reasonably be expected to result in material injury to the Company if he were retained in his position; (iii) continued, willful and deliberate non-performance by Executive of his duties hereunder (other than by reason of Executive's physical or mental illness, incapacity or disability) which has continued for more than thirty (30) days following written notice of such non-performance from the Company; (iv) a material breach by Executive of any of the provisions contained in Section 9 of this Agreement; (v) a material violation by Executive of the Company's employment policies which has continued for more than thirty (30) days following written notice of such violation from the Company; or (vi) willful failure to cooperate with a bona fide internal investigation or an investigation by regulatory or law enforcement authorities, after being instructed by the Company to cooperate, or the willful destruction or failure to preserve documents or other materials known to be relevant to such investigation or the willful inducement of others to fail to cooperate or to produce documents or other materials. In the case of any termination for Cause, the Company shall provide written notice to the Executive setting forth the acts, circumstances and bases that constitute Cause for termination.

(b) By The Company Without Cause.

At any time during the Term, the Company may terminate Executive's employment hereunder without Cause. For purposes of this Agreement, non-renewal of the Term by the Company other than due to Cause shall be treated as a termination of the Executive's employment without Cause.

(c) By The Executive.

At any time during the Term, Executive may terminate his employment hereunder for any reason, including but not limited to Good Reason. For purposes of this Agreement, "Good Reason" shall mean that Executive has complied with the "Good Reason Process" (hereinafter defined) following the occurrence of any of the following events: (i) a substantial diminution or other substantive adverse change, not consented to by Executive, in the nature or scope of Executive's responsibilities, authorities, powers, functions or duties; (ii) a breach by the Company of any of its other material obligations under this Agreement, including but not limited to failure of the Company to make any material payment or provide any material benefit under this Agreement, (iii) the cancellation of the Option due to the failure of the Company to receive shareholder approval of an increase in the number of shares of common stock authorized under the Plan which amendment to the Plan shall include provision for the issuance of shares of common stock underlying the Option, on or prior to October 11, 2018; or (iv) a change in the geographic location at which Executive must perform his services as provided under this Agreement to a location more than thirty miles from the locations selected by the Executive for providing his services from time to time as provided under Section 1(c). A change in the employment of Executive to another affiliate of Company does not in and of itself constitute "Good Reason" (i.e., absent any of the acts, circumstances or bases set forth in (i) through (iv) of this Section 7(c)). "Good Reason Process" shall mean that (A) Executive reasonably determines in good faith that a "Good Reason" event has occurred; (B) Executive notifies the Company in writing of the occurrence of the Good Reason event within ninety (90) days of the occurrence of such event; (C) Executive cooperates in good faith with the Company's efforts, for a period not less than sixty (60) days following such notice, to modify Executive's employment situation in a manner acceptable to Executive and Company; (D) notwithstanding such efforts, one or more of the Good Reason events continues to exist and has not been modified in a manner acceptable to Executive; and (E) Executive terminates his employment no later than sixty (60) days after the end of the sixty (60) day cure period. If the Company cures the Good Reason event in a manner acceptable to Executive during the sixty (60) day period, Good Reason shall be deemed not to have occurred.

(d) Right to Severance.

In the event the Company terminates Executive's employment Without Cause or the Executive terminates employment for Good Reason as provided in Section 7(c) and if Executive executes and does not revoke during any applicable revocation period a general release of all claims against the Company and its affiliates in a form acceptable to the Company (a "Release of Claims") within a reasonable period of time specified by the Company and in compliance with applicable law, following such termination, then in addition to any accrued obligations payable under Section 7(e)(i) below, the Company shall:

(i) Pay to the Executive, within thirty (30) days following the date of termination, an amount equal to one times Executive's Base Salary (determined after disregarding any reduction in Base Salary that constitutes Good Reason), less payroll deductions and all required withholdings;

(ii) Pay to the Executive an amount equal to the product of (A) the amount of the Annual Bonus that would have been payable to the Executive pursuant to Section 3(b) if the Executive was still employed as of December 31st of the then current fiscal year in respect of the fiscal year in which employment termination occurs based on the Company's achievement against the performance goals applicable to such year (after deeming any individual goals to be met at the target level), and (B) the ratio of (x) the number of days elapsed during the fiscal year during which such termination of employment occurs on or prior to the date of such termination to (y) 365, payable as of the same time as annual bonuses are paid to other senior executives; and

(iii) Notify Executive of any right to continue group health plan coverage sponsored by the Company immediately prior to Executive's date of termination pursuant to the provisions of applicable law including, but not limited to, the provisions of the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA"). If Executive elects to receive such continued healthcare coverage, the Company shall directly pay, or reimburse Executive for, the premium for Executive and Executive's covered dependents, less the amount of Executive's monthly premium contributions for such coverage prior to termination, for the period commencing on the first day of the first full calendar month following such employment termination through the earlier of (i) the last day of the month during the first twelve months following the date of termination, following the date the Release of Claims becomes effective and irrevocable and (ii) the date Executive and Executive's covered dependents, if any, become eligible for healthcare coverage under another employer's plan(s). Executive shall notify the Company immediately if Executive becomes covered by a group health plan of a subsequent employer. After the Company ceases to pay premiums pursuant to this subsection, Executive may, if eligible, elect to continue healthcare coverage at Executive's expense in accordance the provisions of COBRA or other applicable law.

For purposes of this Section 7(d), Executive's termination of employment at the end of the Term following an earlier notice of nonrenewal by the Company shall be treated as a termination of the Executive's employment by the Company without Cause as of the last day of the Term.

(e) Upon a termination of the Executive's employment for any reason, (i) the Executive shall be entitled to receive: (A) any portion of the Executive's Base Salary through the date of employment termination not theretofore paid, (B) the Annual Bonus owed to the Executive under Section 3(b) if it remains unpaid as of the date of such termination, (C) any expenses owed to the Executive under Section 3(c) above, (D) any accrued but unused vacation pay owed to the Executive pursuant to Section 3(e) above, and (E) any amount arising from the Executive's participation in, or benefits under, any employee benefit plans, programs or arrangements under Section 3(e), which amounts shall be payable in accordance with the terms and conditions of such employee benefit plans, programs or arrangements.

(f) The payments and benefits described in this Section 7 shall be the only payments and benefits payable in the event of the Executive's termination of employment for any reason.

Section 8. Survival of Obligations.

The obligations of the Executive as set forth in Section 4, Section 7 and Sections 9 through 17 below shall survive the term of this Agreement and the termination of Executive's employment hereunder regardless of the reason(s) therefor.

Section 9. Non-Competition and Conflicting Employment.

(a) During the Term, the Executive shall not, directly or indirectly, either as an Executive, employer, employee, consultant, agent, principal, partner, officer, director, shareholder, member, investor or in any other individual or representative capacity, engage or participate in any business or business related activity of any kind that is in competition in any manner whatever with the business of the Company or any business activity related to the business in which the Company is now involved or becomes involved during the Executive's employment. For these purposes, the current business of the Company is described in the Company's Annual Report on Form 10-K for the year ended December 31, 2016. The Executive also agrees that, during his employment with the Company, he will not engage in any other activities that materially conflict with his obligations to the Company, it being understood that activities approved by the Board under Section 2(b) or otherwise in writing shall not be considered to violate this Section 9(a).

(b) As a material inducement to the Company to continue the employment of the Executive, and in order to protect the Company's Confidential Information and good will, the Executive agrees that:

(i) For a period of twelve (12) months following termination of the Executive's employment with the Company or its affiliates for any reason, Executive will not directly or indirectly solicit or divert or accept business relating in any manner to Competing Products or to products, processes or services of the Company, from any of the customers or accounts of the Company with which the Executive had any contact as a result of Executive's employment with the Company; and

(c) For a period of twelve (12) months after termination of Executive's employment with the Company or its affiliates for any reason, Executive will not (A) render services directly or indirectly, as an Executive, consultant or otherwise, to any Competing Organization in connection with research on or the acquisition, development, production, distribution, marketing or providing of any Competing Product, or (B) own any interest in any Competing Organization except as an investor or stockholder of more than 2% of the equity securities of any entity:

(i) "Competing Products" means any product, process, or service of any person or organization other than the Company, in existence or under development (a) which is identical to, substantially the same as, or an adequate substitute for any product, process or service of the Company in existence or under development, based on any patent or patent application (provisional or otherwise), or other intellectual property of the Company about which the Executive acquires Confidential Information, and (b) which is (or could reasonably be anticipated to be) marketed or distributed in such a manner and in such a geographic area as to actually compete with such product, process or service of the Company; and

(ii) "Competing Organization" means any person or organization, including the Executive, engaged in, or about to become engaged in, research on or the acquisition, development, production, distribution, marketing or providing of a Competing Product.

(d) The parties agree that the Company is entitled to protection of its interests in these areas. The parties further agree that the limitations as to time, geographical area, and scope of activity to be restrained do not impose a greater restraint upon Executive than is necessary to protect the goodwill or other business interest of the Company. The parties further agree that in the event of a violation of this Covenant Not To Compete, that the Company shall be entitled to the recovery of damages from Executive and injunctive relief against Executive for the breach or violation or continued breach or violation of this Covenant. The Executive agrees that if a court of competent jurisdiction determines that the length of time or any other restriction, or portion thereof, set forth in this Section 9 is overly restrictive and unenforceable, the court may reduce or modify such restrictions to those which it deems reasonable and enforceable under the circumstances, and as so reduced or modified, the parties hereto agree that the restrictions of this Section 9 shall remain in full force and effect. The Executive further agrees that if a court of competent jurisdiction determines that any provision of this Section 9 is invalid or against public policy, the remaining provisions of this Section 9 and the remainder of this Agreement shall not be affected thereby, and shall remain in full force and effect.

Section 10. Confidentiality.

(a) (a) Executive recognizes and acknowledges that he will have access to certain information of members of the Company and that such information is confidential and constitutes valuable, special and unique property of such members of the Company. The parties agree that the Company has a legitimate interest in protecting the Confidential Information , as defined below. The parties agree that the Company is entitled to protection of its interests in the Confidential Information. The Executive shall not at any time, either during his employment and for seven (7) years after the termination of his employment with the Company for any reason, or indefinitely to the extent the Confidential Information constitutes a trade secret under applicable law, disclose to others, use, copy or permit to be copied, except in pursuance of his duties for and on behalf of the Company, its successors, assigns or nominees, any Confidential Information of any member of the Company (regardless of whether developed by the Executive) without the prior written consent of the Company. Executive acknowledges that the use or disclosure of the Confidential Information to anyone or any third party could cause monetary loss and damages to the Company as well as irreparable harm. The parties further agree that in the event of a violation of this covenant against non-use and non-disclosure of Confidential Information, that the Company shall be entitled to a recovery of damages from Executive and/or to obtain an injunction against Executive for the breach or violation, continued breach, threatened breach or violation of this covenant.

(b) As used herein, the term "Confidential Information" with respect to any person means any secret or confidential information or know-how and shall include, but shall not be limited to, plans, financial and operating information, customers, supplier arrangements, contracts, costs, prices, uses, and applications of products and services, results of investigations, studies or experiments owned or used by such person, and all apparatus, products, processes, compositions, samples, formulas, computer programs, computer hardware designs, computer firmware designs, and servicing, marketing or manufacturing methods and techniques at any time used, developed, investigated, made or sold by such person, before or during the term of this Agreement, that are not readily available to the public or that are maintained as confidential by such person. The Executive shall maintain in confidence any Confidential Information of third parties received as a result of his employment with the Company in accordance with the Company's obligations to such third parties and the policies established by the Company.

(c) As used herein, "Confidential Information" with respect to the Company means any Company proprietary information, technical data, trade secrets, know-how or other business information disclosed to the Executive by the Company either directly or indirectly in writing, orally or by drawings or inspection or unintended view of parts, equipment, data, documents or the like, including, without limitation:

(i) Medical and drug research and testing results and information, research and development techniques, processes, methods, formulas, trade secrets, patents, patent applications, computer programs, software, electronic codes, mask works, inventions, machines, improvements, data, formats, projects and research projects;

(ii) Information about costs, profits, markets, sales, pricing, contracts and lists of customers, distributors and/or vendors and business, marketing and/or strategic plans;

(iii) Forecasts, unpublished financial information, budgets, projections, and customer identities, characteristics and agreements as well as all business opportunities, conceived, designed, devised, developed, perfected or made by the Executive whether alone or in conjunction with others, and related in any manner to the actual or anticipated business of the Company or to actual or anticipated areas of research and development; and

(iv) Executive personnel files and compensation information.

(d) Notwithstanding the foregoing, Confidential Information as defined in Sections 10(b) and (c) does not include any of the foregoing items which (i) has become publicly known or made generally available to the public through no wrongful act of Executive; (ii) has been disclosed to Executive by a third party having no duty to keep Company matter confidential; (iii) has been developed by Executive independently of employment with the company; (iv) has been disclosed by the Company to a third party without restriction on disclosure; (v) has been disclosed with the Company's written consent, or (vi) the Company's investors, shareholders and other capital sources.

(e) Executive hereby acknowledges and agrees that all Confidential Information shall at all times remain the property of the Company.

(f) Executive agrees that Executive will not improperly use or disclose any Confidential Information, proprietary information or trade secrets of any former employer or other person or entity with which Executive has an agreement or duty to keep in confidence information acquired by Executive and that Executive will not bring onto Company premises any unpublished document or proprietary information belonging to any such employer, person or entity unless consented to in writing by such employer, person or entity.

(g) Executive recognizes that the Company has received and in the future will receive from third parties their confidential or proprietary information subject to a duty on the Company's part to maintain the confidentiality of such information and to use it only for certain limited purposes. Executive agrees to hold all such confidential or proprietary information in the strictest of confidence and not to disclose it to any person, firm or entity or to use it except as necessary in carrying out Executive's work for the Company consistent with Company's agreement with such third party.

(h) Executive represents and warrants that from the time of the Executive's first contact with the Company, Executive has held in strict confidence all Confidential Information and has not disclosed any Confidential Information directly or indirectly to anyone outside the Company, or used, copied, published or summarized any Confidential Information, except to the extent otherwise permitted under the terms of this Agreement.

(i) Executive will not disclose to the Company or use on its behalf any confidential information belonging to others and Executive will not bring onto the premises of the Company any confidential information belonging to any such party unless consented to in writing by such party.

Section 11. Inventions.

(a) Attached hereto as Exhibit A is a list describing all ideas, processes, trademarks, service marks, inventions, designs, technologies, computer hardware or software, original works of authorship, formulas, discoveries, patents, copyrights, copyrightable works, products, marketing and business ideas, and all improvements, know-how, data rights, and claims related to the foregoing, whether or not patentable, registrable or copyrightable, which were conceived, developed or created by Executive prior to Executive's employment or first contact with Company (collectively referred to herein as "Prior Inventions"), (A) which belong to Executive, (B) which relate to the Company's current or contemplated business, products or research and development, and (C) which are not assigned to the Company hereunder. If there is no Exhibit A or no items thereon, the Executive represents that there are no such Prior Inventions. If in the course of Executive's employment with the Company, the Executive incorporates or embodies into a Company product, service or process a Prior Invention owned by the Executive or in which the Executive has an interest, the Company is hereby granted and shall have a nonexclusive, royalty-free, irrevocable, perpetual, world-wide license to make, have made, modify, use and sell such Prior Invention as part of or in connection with such product, service or process.

(b) Executive agrees that Executive will promptly make full, written disclosure to the Company and will hold in trust for the sole right and benefit of the Company, and the Executive hereby assigns to the Company, or its designee, all of the Executive's right, title and interest in and to any and all ideas, process, trademarks, service marks, inventions, designs, technologies, computer hardware or software, original works of authorship, formulas, discoveries, patents, copyrights, copyrightable works, products, marketing and business ideas, and all improvements, know-how, data, rights and claims related to the foregoing, whether or not patentable, registrable or copyrightable, which Executive may, on or after the Effective Date of this Agreement, solely or jointly with others conceive or develop or reduce to practice, or cause to be conceived or developed or reduced to practice, during the period of time the Executive is in the employ of the Company (collectively referred to herein as "Intellectual Property Items"); and the Executive further agrees that the foregoing shall also apply to Intellectual Property Items which relate to the business of the Company or to the Company's anticipated business as of the end of the Executive's employment and which are conceived, developed or reduced to practice during a period of one year after the end of such employment. Without limiting the foregoing, the Executive further acknowledges that all original works of authorship which are made by Executive (solely or jointly with others) within the scope of Executive' employment and which are protectable by copyright are works made for hire as that term is defined in the United States Copyright Act.

(c) Executive agrees to keep and maintain adequate and current written records of all Intellectual Property Items made by Executive (solely or jointly with others) during the term of Executive's employment with the Company. The records will be in the form of notes, sketches, drawings and any other format that may be specified by the Company. The records will be available to, and remain the sole property of, the Company at all times.

Section 12. Return of Company Property.

Executive agrees that, at any time upon request of the Company, and, in any event, at the time of leaving the Company's employ, Executive will deliver to the Company (and will not keep originals or copies in Executive's possession or deliver them to anyone else) any and all devices, records, data, notes, reports, proposals, lists, correspondence, specifications, drawings, blueprints, sketches, material, equipment or other documents or property, or reproduction of any of the aforementioned items, containing Confidential Information or otherwise belonging to the Company, its successors or assigns, whether prepared by the Executive or supplied to the Executive by the Company. Notwithstanding the foregoing, it is understood that names and contacts in the Executive's address book acquired both prior to and during employment, including shareholders of the Company, will remain property of the Executive who will not be restricted from doing business with them subject to the limitations Sections 10 and 14 hereof and applicable law.

Section 13. Non-Solicitation.

Executive agrees that Executive shall not, during Executive's employment or other involvement with the Company and for a period of twelve (12) months immediately following the termination of the Executive's employment with the Company, for any reason, whether with or without cause, (i) either directly or indirectly solicit or take away, or attempt to solicit or take away executives of the Company, either for the Executive's own business or for any other person or entity and/or (ii) either directly or indirectly recruit, solicit or otherwise induce or influence any investor, lessor, supplier, customer, agent, representative or any other person which has a business relationship with the Company to discontinue, reduce or modify such employment, agency or business relationship with the Company .

Section 14. Publications.

Executive agrees that Executive will, in advance of publication, provide the Company with copies of all writings and materials which Executive proposes to publish during the term of Executive's employment and for twenty-four (24) months thereafter. Executive also agrees that Executive will, at the Company's request and sole discretion, cause to be deleted from such writings and materials any information the Company believes discloses or will disclose Confidential Information. The Company's good faith judgment in these matters will be final. The Executive will also, at the Company' request and in its sole discretion, cause to be deleted any reference whatsoever to the Company from such writings and materials.

Section 15. Equitable Remedies.

Executive agrees that any damages awarded the Company for any breach of Sections 9 through 14 of this Agreement by Executive would be inadequate. Accordingly, in addition to any damages and other rights or remedies available to the Company, the Company shall be entitled to obtain injunctive relief from a court of competent jurisdiction temporarily, preliminarily and permanently restraining and enjoining any such breach or threatened breach and to specific performance of any such provision of this Agreement. In the event that either party commences litigation against the other under this Agreement the prevailing party in said litigation shall be entitled to recover from the other all costs and expenses incurred to enforce the terms of this Agreement and/or recover damages for any breaches thereof, including without limitation reasonable attorneys' fees.

Section 16. Representations and Warranties.

(a) Executive represents and warrants as follows that: (i) Executive has no obligations, legal or otherwise, inconsistent with the terms of this Agreement or with the Executive's undertaking a relationship with the Company; and (ii) Executive has not entered into, nor will Executive enter into, any agreement (whether oral or written) in conflict with this Agreement.

(b) The Company represents and warrants to the Executive that this Agreement and the RSUs and Options grant have been duly authorized by the Company's Board of Directors and are the valid and binding obligations of the Company, enforceable in accordance with their respective terms.

Section 17. Miscellaneous.

(a) Entire Agreement. This Agreement, the exhibits attached hereto, and the RSUs and Option granted concurrently herewith under Section 5(a) hereof, contain the entire understanding of the parties and supersede all previous contracts, arrangements or understandings, express or implied, between the Executive and the Company with respect to the subject matter hereof or his engagement by the Company as Chief Executive Officer. No agreements or representations, oral or otherwise, express or implied, with respect to the subject matter hereof have been made by either party which are not expressly set forth in this Agreement or in the attached exhibits.

(b) Section Headings. The section headings herein are for the purpose of convenience only and are not intended to define or limit the contents of any section.

(c) Severability. If any provision of this Agreement shall be declared to be invalid or unenforceable, in whole or in part, the remainder of this Agreement shall be amended to provide the parties with the equivalent of the same rights and obligations as provided in the original provisions of this Agreement.

(d) No Oral Modification; Waiver or Discharge. No provisions of this Agreement may be modified, waived or discharged orally, but only by a waiver, modification or discharge in writing signed by the Executive and such officer as may be designated by the Board of Directors of the Company to execute such a waiver, modification or discharge. No waiver by either party hereto at any time of any breach by the other party hereto of, or failure to be in compliance with, any condition or provision of this Agreement to be performed by such other party shall be deemed a waiver of similar or dissimilar provisions or conditions at the time or at any prior or subsequent time.

(e) Invalid Provisions. Should any portion of this Agreement be adjudged or held to be invalid, unenforceable or void, such holding shall not have the effect of invalidating or voiding the remainder of this Agreement and the parties hereby agree that the portion so held invalid, unenforceable or void shall, if possible, be deemed amended or reduced in scope, or otherwise be stricken from this Agreement to the extent required for the purposes of validity and enforcement

(f) Execution In Counterparts. The parties may sign this Agreement in counterparts, all of which shall be considered one and the same instrument. Facsimile transmissions, or electronic transmissions in .pdf format, of any executed original document and/or retransmission of any executed facsimile or .pdf transmission shall be deemed to be the same as the delivery of an executed original of this Agreement.

(g) Governing Law And Performance. This Agreement shall be governed, construed, interpreted and enforced in accordance with the substantive laws of the Commonwealth of Massachusetts, without giving effect to any choice of law or conflict of law provision or rule (whether of the Commonwealth of Massachusetts or any other jurisdiction) that would cause the application of the law of any jurisdiction other than the Commonwealth of Massachusetts. Any legal action or proceeding with respect to this Agreement shall be brought in the courts of the Commonwealth of Massachusetts or of the United States of America for the District of Massachusetts. By execution and delivery of this Agreement, each of the parties hereto accepts for itself and in respect of its property, generally and unconditionally, the exclusive jurisdiction of the aforesaid courts. ANY ACTION, DEMAND, CLAIM, OR COUNTERCLAIM ARISING UNDER OR RELATING TO THIS AGREEMENT SHALL BE RESOLVED BY A JUDGE ALONE AND EACH OF COMPANY AND EXECUTIVE WAIVES ANY RIGHT TO A JURY TRIAL THEREOF.

(h) Successor and Assigns. This Agreement shall be binding on and inure to the benefit of the successors in interest of the parties, including, in the case of the Executive, the Executive's heirs, executors and estate. The Executive may not assign Executive's obligations under this Agreement. Any successor to the Company (whether direct or indirect and whether by purchase, merger, consolidation, liquidation or otherwise) to all or substantially all of the Company's business and/or assets shall assume the obligations under this Agreement and agree expressly to perform the obligations under this Agreement in the same manner and to the same extent as the Company would be required to perform such obligations in the absence of a succession. For all purposes under this Agreement, the term "Company" shall include any successor to the Company's business and/or assets which executes and delivers the assumption agreement described in this Section 17(h) or which becomes bound by the terms of this Agreement by operation of law.

(i) Notices. Any notices or other communications provided for hereunder may be made by hand, by certified or registered mail, postage prepaid, return receipt requested, or by nationally recognized express courier services provided that the same are addressed to the party required to be notified at its address first written above, or such other address as may hereafter be established by a party by written notice to the other party. Notice shall be considered accomplished on the date delivered, three days after being mailed or one day after deposit with the express courier, as applicable.

Section 18. Section 409A.

(a) It is intended that any compensation or benefits under this Agreement satisfy, to the greatest extent possible, the exemptions from the application of Section 409A of the Internal Revenue Code of 1986, as amended ("Section 409A") provided under Treasury Regulations Sections 1.409A-1(b), and this Agreement will be construed to the greatest extent possible as consistent with those provisions, and to the extent not so exempt, this Agreement (and any definitions hereunder) will be construed in a manner that complies with Section 409A. For purposes of Section 409A, the Executive's right to receive any installment payments under this Agreement shall be treated as a right to receive a series of separate payments and, accordingly, each installment payment hereunder shall at all times be considered a separate and distinct payment. Severance benefits under Section 7(d) shall not commence until the Executive has a "separation from service" for purposes of Section 409A.

(b) To the extent that any reimbursement of expenses or in-kind benefits constitutes deferred compensation under Section 409A, such reimbursement or benefit shall be provided no later than December 31 of the year following the year in which the expense was incurred. The amount of expenses reimbursed in one year shall not affect the amount eligible for reimbursement in any subsequent year. The amount of any in-kind benefits provided in one year shall not affect the amount of in-kind benefits provided in any other year.

(c) If the Executive is deemed at the time of his separation from service to be a specified employee for purposes of Section 409A(a)(2)(B)(i) of the Code, to the extent delayed commencement of any portion of the compensation and benefits to which the Executive is entitled under this Agreement is required in order to avoid a prohibited distribution under Section 409A(a)(2)(B)(i) of the Code, such portion of the Executive's termination benefits shall be provided to the Executive immediately after the earlier of (A) the expiration of the six-month period measured from the date of the Executive's separation from service with the Company (as such term is defined in the Treasury Regulations issued under Section 409A of the Code) or (B) the date of the Executive's death in a lump sum, and any remaining payments due under the Agreement shall be paid as otherwise provided herein.

Section 19. Limitation of Payments upon Certain Events.

(a) Limitation on Payments. Notwithstanding anything in this Agreement to the contrary, if any payment or distribution Executive would receive pursuant to this Agreement or otherwise ("Payment") would (a) constitute a "parachute payment" within the meaning of Section 280G of the Code), and (b) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "Excise Tax"), then the Company shall cause to be determined, before any amounts of the Payment are paid to Executive, which of the following alternative forms of payment would maximize Executive's after-tax proceeds: (i) payment in full of the entire amount of the Payment (a "Full Payment"), or (ii) payment of only a part of the Payment so that Executive receives that largest Payment possible without being subject to the Excise Tax (a "Reduced Payment"), whichever of the foregoing amounts, taking into account the applicable federal, state and local income taxes and the Excise Tax (all computed at the highest marginal rate, net of the maximum reduction in federal income taxes which could be obtained from a deduction of such state and local taxes), results in Executive's receipt, on an after-tax basis, of the greater amount of the Payment, notwithstanding that all or some portion the Payment may be subject to the Excise Tax.

(b) The independent registered public accounting firm engaged by the Company for general audit purposes as of the day prior to the date the first Payment is due shall make all determinations required to be made under this Section 19. If the independent registered public accounting firm so engaged by the Company is serving as accountant or auditor for the individual, group or entity effecting the transaction, the Company shall appoint a nationally recognized independent registered public accounting firm to make the determinations required hereunder. The Company shall bear all expenses with respect to the determinations by such independent registered public accounting firm required to be made hereunder.

(c) The independent registered public accounting firm engaged to make the determinations hereunder shall provide its calculations, together with detailed supporting documentation, to the Company and Executive at such time as requested by the Company or Executive. If the independent registered public accounting firm determines that no Excise Tax is payable with respect to a Payment, either before or after the application of the Reduced Payment, it shall furnish the Company and Executive with an opinion reasonably acceptable to Executive that no Excise Tax will be imposed with respect to such Payment. Any good faith determinations of the accounting firm made hereunder shall be final, binding and conclusive upon the Company and Executive.

IN WITNESS WHEREOF, the parties hereto have executed this Amended and Restated Employment Agreement under seal as of the date and year first above written.

Company:	Executive:
Xenetic Biosciences Inc.,	
/s/ James Parslow By: James Parslow Chief Financial Officer	/s/ Jeffrey Eisenberg By: Jeffrey Eisenberg

Exhibit 10.46

[***] Indicates portions of this exhibit that have been omitted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.

EXECUTION VERSION

RIGHT TO SUBLICENSE AGREEMENT

This Right to Sublicense Agreement ("Agreement") is made and entered into as of October 27, 2017 by and between Baxalta Incorporated, Baxalta US Inc., and Baxalta GmbH (collectively, with their Affiliates, "Baxalta") and Xenetic Biosciences, Inc. (with its Affiliates, "Xenetic") (with Baxalta and Xenetic being the "Parties" and each individually, a "Party").

WITNESSETH

WHEREAS, the Parties acknowledge the existence of an Exclusive Research, Development, and License Agreement ("Original Agreement") entered into between Baxter Healthcare SA and Baxter Healthcare Corporation and Lipoxen Technologies Limited on August 15, 2005 and subsequently amended as follows: Amendment No. 1 of August 15, 2005; Letter Amendment of December 13, 2005 ("Amendment No. 2"); Amendment No. 3 of May 2009; Amendment No. 4 of August 10, 2010; Amendment No. 5 of September 15, 2010; and Amendment No. 6 of January 29, 2014 (collectively, the "Amendments," the Original Agreement as amended by the Amendments is referred to as the "Exclusive Agreement");

WHEREAS, effective July 1, 2015, Baxter International Inc. separated into two publicly-traded companies, one of which became Baxalta Incorporated;

WHEREAS, Baxalta Incorporated, Baxalta US Inc., and Baxalta GmbH retained Baxter International Inc.'s hemophilia treatment projects and products, including the Exclusive Agreement;

WHEREAS, U.K.-based Lipoxen PLC changed its name to Xenetic Biosciences PLC in 2011, and in 2014 Xenetic Biosciences PLC became U.S.-based Xenetic Biosciences, Inc.;

WHEREAS, Xenetic has certain rights in Patents listed in Exhibit A ("Xenetic Patents") that may cover the composition, manufacture, sale, or import of Licensed Products, or are necessary to develop, make, have made, use, sell, have sold, and import Licensed Products;

WHEREAS, notwithstanding any limitations or conditions set forth in the Exclusive Agreement, Baxalta wishes to sublicense the Xenetic Patents [***]; and

WHEREAS, notwithstanding any limitations or conditions set forth in the Exclusive Agreement, and subject to the limitations and conditions of this Agreement, Xenetic wishes to grant Baxalta the right to sublicense the Xenetic Patents [***].

NOW, THEREFORE, in consideration of the above promises and mutual covenants hereinafter contained, the Parties agree as follows:

SECTION I — DEFINITIONS

"Affiliate" means, with respect to a Party, any Person that directly or indirectly, through one or more intermediates, Controls, is Controlled by, or is under common Control with such Party. For purposes of this Agreement, "Control" means (a) direct or indirect legal or beneficial ownership of fifty percent (50%) or more of (i) the voting equity of such entity or (ii), in the case of a non-corporate entity, equivalent interests, or (b) the power to otherwise direct the business activities of a Person.

"Business Day" means any day other than a Saturday, a Sunday, or a day on which commercial banks located in New York, New York are authorized or required by applicable law to remain closed.

"Calendar Day" means all days in a month, including weekends and holidays.

"Effective Date" is the date on which all Parties have signed this Agreement.

"EU" means the European Union, including the United Kingdom.

"Factor VIII" means a recombinantly produced Factor VIII molecule, including the full-length human Factor VIII protein and any equivalents thereof, including any variants containing any derivatives, mutations, deletions, insertions, or substitutions.

"Licensed Patents" means (a) the Xenetic Patents; (b) any and all Patents existing or subsequently issuing from applications (i) from which any of the Xenetic Patents claim direct or indirect priority, (ii) which claim direct or indirect priority from any of the Xenetic Patents, or (iii) which share common priority with any of the Xenetic Patents; (c) any and all Patents existing or subsequently issuing from continuations, divisionals, continuations-in-part, reexaminations, substitutes, requests for continued examination, reissues, extensions, supplementary protection certificates, and renewals of any Patents or applications described in subsection (a) or (b) above; (d) any foreign counterparts, foreign related applications, or foreign related Patents of any of the foregoing; and (e) no others. Licensed Patents does not include any Patents owned or controlled by Baxalta or Xenetic not expressly set forth in this definition.

"Licensed Product" means [***].

"Manufacture" means to develop, make, have made, manufacture, or have manufactured a biologic or pharmaceutical product, including any ingredient thereof, and "Manufactured" shall have a corresponding meaning.

"Market" means to offer, have offered, sell, have sold, offer to sell, or have offered for sale a biologic or pharmaceutical product or to use, commercially-launch or distribute, have commercially-launched or distributed such product for such purposes, and "Marketing" shall have a corresponding meaning.

"Net Sales" shall have the same meaning as set forth in the [***] Agreement. The definition of Net Sales upon entering into the [***] Agreement is as set forth in Exhibit B.

"[***] Agreement" means the agreement, or series of agreements, relating to Licensed Products to be entered into by and between Baxalta and [***], which includes a sublicense to the Licensed Patents, and includes obligations for [***] to (a) make an up-front payment to Baxalta within five (5) Business Days of the parties thereto executing such agreement (the "Up Front Payment"), (b) make quarterly royalty payments to Baxalta which are a function of Net Sales ("[***] Royalties"), and (c) make a quarterly report in connection with such royalty payments ("[***] Report").

"Patent(s)" means (a) all classes or types of patents throughout the world, including utility patents, utility models, design patents, invention certificates, reexamination certificates, reissues and renewals as well as foreign equivalents thereof; and (b) all applications (including provisional and non-provisional applications), continuations, divisionals, continuations-in-part, reissues, extensions, supplementary protection certificates, renewals, re-examinations, as well as foreign equivalents thereof. The term "Patents" does not include any copyrights, trademarks, mask work rights, or trade secret rights.

"Person" means any individual, trust, corporation, partnership, joint venture, limited liability company, association, unincorporated organization, or other legal entity.

"Third Party" means any Person other than a Party to this Agreement or an Affiliate of a Party to this Agreement.

"U.S." or "US" means the United States of America and its territories.

"U.S. Launch Date" means [***].

"Value Added Tax" or "VAT" means (a) in relation to any jurisdiction within the EU, the tax imposed by the EC Council Directive on the common system of value added tax (2006/112/EC) and any successor or equivalent legislation and any national legislation implementing that directive together with legislation supplemental thereto and the equivalent tax (if any) in that jurisdiction; and (b) in any other jurisdiction, any other value added, goods and services, consumption or similar tax chargeable on the supply or deemed supply of goods or services under applicable legislation or regulation; but, in each event, excluding any U.S. sales tax.

"Xenetic Patents" means the Patents as set forth in Exhibit A.

SECTION II — LICENSE

2.1 Right to Sublicense. Notwithstanding any limitations or conditions set forth in the Exclusive Agreement, Xenetic hereby grants to Baxalta and its Affiliates the right to grant a nonexclusive sublicense under the Licensed Patents to [***]:

(a) Manufacture the Licensed Product anywhere in the world on or after the Effective Date;

(b) Market the Licensed Product anywhere in the world other than the U.S. on or after the Effective Date; and

(c) Market the Licensed Product in the U.S. on or after the U.S. Launch Date.

(individually and collectively, the "Sublicense").

2 . 2 Survival of Sublicense. For the avoidance of doubt, any Sublicense of the Licensed Patents granted to [***] shall survive termination of the Exclusive Agreement or this Agreement for any reason.

[***] Indicates portions of this exhibit that have been omitted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.

EXECUTION VERSION

SECTION III CONSIDERATION

3.1 Payment. Provided that Baxalta receives the Up Front Payment, Baxalta US Inc. shall pay Xenetic within fifteen (15) Business Days after receiving the Up Front Payment a lump-sum, non-refundable payment of Seven Million Five Hundred Thousand U.S. Dollars ($7,500,000)("Milestone Payment").

3.2 Royalties. Provided that Baxalta receives the [***] Royalties Baxalta US Inc. shall pay Xenetic a [***] percent ([***]%) royalty in U.S. Dollars based on the [***] Royalties within fifteen (15) Business Days after receiving the [***] Royalties throughout the Term.

3.3 No Other Consideration. No other payments shall be due or payable to Xenetic under this Agreement or the Exclusive Agreement in connection with the Sublicense.

3.4 Contingency. For the avoidance of doubt, Baxalta shall not have any obligation (a) to make the payment contemplated in Section 3.1 if Baxalta does not receive the Up Front Payment, nor (b) to make any royalty payment(s) contemplated in Section 3.2 if Baxalta does not receive payment of the corresponding [***] Royalty. Baxalta agrees to use reasonable efforts to promptly collect any amounts owed to it under the [***] Agreement and will keep Xenetic informed in reasonable detail.

3.5 Method of Payment. All payments from Baxalta US Inc. to Xenetic under this Section III shall be made by wire transfer in U.S. Dollars of immediately-available funds to a bank account designated by Xenetic in writing.

3.6 Reporting Obligations. Baxalta shall prepare and provide to Xenetic written reports, which shall be subject to the confidentiality obligations in Section V (the "Royalty Report"). Such Royalty Report shall be provided within ten (10) Business Days after Baxalta receives the [***] Reports. Each Royalty Report shall report Net Sales, as reported in the [***] Report, and the Royalties owed to Xenetic. If Baxalta needs additional time to reconcile [***] written report(s) to ensure accurate reporting, Baxalta shall immediately notify Xenetic of the need for additional time and the parties will mutually agree on a reasonable extension for providing the written reports.

3.7 Currency and currency conversion. Currency and currency conversion calculations shall be the same as applied to Baxalta under the [***] Agreement.

3.8 Records. Baxalta will maintain the [***] Reports for at least three (3) years after submission of the applicable Royalty Report.

3.9 Audit Rights. Upon reasonable prior written notice to Baxalta, Baxalta will provide access to the [***] Reports to a third party accounting firm selected by Xenetic and reasonably acceptable to Baxalta. Baxalta will require any such accounting firm to enter into a confidentiality agreement and will not permit the disclosure of the [***] Reports to any third party including Xenetic. The review will occur: (a) during normal business hours; (b) in a manner reasonably designed to facilitate Xenetic's review or audit without unreasonable disruption to Baxalta's business; and (c) no more than once each calendar year during the Term and for a period of three (3) years thereafter. Baxalta will promptly pay to Xenetic the amount of any uncontested underpayment determined by the review or audit, and accrued interest. If the review or audit determines that Baxalta has underpaid any payment by five percent (5%) or more, then Baxalta will also promptly pay the costs and expenses of Xenetic and its accountants in connection with the review or audit.

3.10 Interest. All amounts that are not paid by Baxalta when due will accrue interest from the date due until paid at a rate equal to one and one half percent (1.5%) per year (or the maximum allowed by law, if less).

3.11 Value Added Tax . All payments or amounts due under this Agreement, whether monetary or non-monetary, are exclusive of VAT/Sales Tax and their equivalents.

3.12 Withholding Tax. The withholding of taxes shall be governed by Section 9.5 of the Exclusive Agreement.

SECTION IV — WAIVER

To the extent the Exclusive Agreement contains or imposes any restrictions, limitations or conditions on either (i) Baxalta's ability to grant a sublicense under the Licensed Patents, or (ii) the terms and conditions of any sublicense of the Licensed Patents, Xenetic hereby waives all such restrictions, limitations, and conditions in connection with the Sublicense.

SECTION V — CONFIDENTIALITY

The Parties agree that (1) this Agreement and (2) any information that is shared regarding the [***] Agreement or [***] performance thereof is confidential and no Party will disclose any of its contents, including in any press release, unless (a) required by applicable laws, in which case the Party compelled to disclose will provide prior notice to the other Party in order to afford such other Party the opportunity to prevent or seek confidential treatment of such disclosure, or (b) required by stock exchange rules. Notwithstanding the foregoing, either Party may disclose this Agreement to its attorneys, advisors, consultants, agents, and representatives who are subject to obligations of confidentiality consistent with this Agreement.

SECTION VI — GOVERNING LAW

This Agreement shall be construed, and the relationship between the Parties determined, under the laws of Delaware, notwithstanding any choice-of-law principle that might dictate a different governing law. Baxalta and Xenetic agree (a) that all disputes and litigation regarding this Agreement, its construction and matters connected with its performance be subject to the exclusive jurisdiction of the state and federal courts located in Wilmington, Delaware (the "Court"); and (b) to submit any disputes, matters of interpretation, controversies, or enforcement actions arising with respect to the subject matter of this Agreement exclusively to the Court. The Parties hereby waive any challenge to the jurisdiction or venue of the Court over these matters.

SECTION VII — TERM

7.1 Term. The term of this Agreement shall commence upon the Effective Date and shall continue on a country by country basis, until the expiration of the last-to-expire Licensed Patents or upon certification from Baxalta that it is not receiving compensation for sales of Licensed Products in a country whichever is later ("Term") regardless of the termination or expiration of the Exclusive Agreement.

7.2 Termination for Failure to Receive Up Front Payment. In the event that Baxalta does not receive the Up Front Payment under the [***] Agreement within such fifteen (15) Business Day period, Baxalta shall promptly advise Xenetic and the parties will meet and confer within ten (10) Business Days to discuss and agree on a reasonable cure plan. In the event that the [***] Agreement is terminated as a result of failure to make the Up Front Payment, this Agreement and any Sublicenses granted pursuant to this Agreement, shall be terminated.

[***] Indicates portions of this exhibit that have been omitted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.

EXECUTION VERSION

SECTION VIII — OTHER TERMS

8.1 Construction/Interpretation. The headings and captions used in this Agreement are solely for the convenience of reference and shall not affect its interpretation. The term "including" means "including, without limitation," and "herein," "hereof," and "hereunder" refer to this Agreement. The word "will" shall be construed to have the same meaning and effect as the word "shall." The Parties agree and acknowledge that this Agreement is the product of both Parties and shall not be construed against either Party.

8.2 Objections. If any administrative, governmental, or judicial body finds that this Agreement is invalid, unenforceable, or illegal under the antitrust, competition or trade regulation laws of the United States, the Parties agree to confer promptly and in good faith in order to modify this Agreement to overcome such finding; provided that nothing contained therein shall be deemed to require a Party to agree to any modification that materially affects the economic value of the transactions contemplated hereby.

8.3 No Agency. Nothing in this Agreement is intended or shall be deemed to constitute a partnership, agency, employer-employee, or joint venture relationship between the Parties. No Party shall incur any debts or make any commitments for any other. There is no fiduciary duty or special relationship of any kind between the Parties to this Agreement. Each Party expressly disclaims any reliance on any act, word, or deed of any other Party in entering into this Agreement.

8.4 No Further License; No Third-Party Rights. Nothing contained in this Agreement shall be construed as conferring any right to a license or to otherwise use any patent, trademark, service name, service mark, trade dress, trade secret, or other intellectual property belonging to any Party, except as expressly provided in this Agreement. Nothing in this Agreement is intended to confer upon any Person, other than the Parties, any rights, remedies, obligations or liabilities under or by reason of this Agreement, except as expressly provided in this Agreement.

8.5 Sophisticated Parties Represented by Counsel. The Parties each acknowledge, accept, warrant and represent that (a) they are sophisticated parties represented at all relevant times during the negotiation and execution of this Agreement by counsel of their choice, and that they have executed this Agreement with the consent and on the advice of such independent legal counsel; and (b) they and their counsel have determined through independent investigation and robust, arm's-length negotiation that the terms of this Agreement shall exclusively embody and govern the subject matter of this Agreement.

8.6 Severability. If any provision of this Agreement is held to be illegal or unenforceable, such provision shall be limited or eliminated to the minimum extent necessary so that the remainder of this Agreement will continue in full force and effect and be enforceable. The Parties agree to negotiate in good faith an enforceable substitute provision for any invalid or unenforceable provision that most nearly achieves the intent of such provision.

8.7 Entire Agreement. The Parties acknowledge, accept, warrant and represent that (a) this is an enforceable agreement; (b) this Agreement embodies the entire and only understanding of each Party with respect to the Sublicense, and merges, supersedes and cancels all previous representations, warranties, assurances, communications, conditions, definitions, understandings or any other statement, express, implied, or arising by operation of law, whether oral or written, whether by omission or commission between and among them with respect to the foregoing subject matter of this Agreement; (c) no oral explanation or oral information by either Party hereto shall alter the meaning or interpretation of this Agreement; (d) the terms and conditions of this Agreement may be altered, modified, changed or amended only by a written agreement executed by duly-authorized representatives of the parties and specifically referencing this Section 8.8; and (f) none of them (nor their respective counsel) shall be deemed to be the draftsman of this Agreement in any action which may hereafter arise with respect to this Agreement.

8.8 Representations and Warranties. Each Party represents and warrants that it has the full right and authority to enter into this Agreement on behalf of itself and all of its Affiliates and to comply with all of the terms and conditions and fulfill all of its obligations set forth in this Agreement. Each Party shall cause all of its successors, assigns, transferees, Affiliates and successors, assigns and transferees of its Affiliates, to comply with all of the terms and conditions of this Agreement and to fulfill all of its obligations set forth in this Agreement, including the granting of all rights, licenses, covenants and releases set forth in this Agreement, and each Party shall be directly liable to the other Party for any breach of this Agreement by any of its successors, assigns, transferees or Affiliates or any successors, assigns or transferees of its Affiliates, including any failure by any such Person to grant any right, license, covenant or release set forth in this Agreement. Except for the changes necessary to effectuate this Agreement, the Parties acknowledge and agree that the Exclusive Agreement remains in force on its terms.

8.9 Modification: Waiver. No modification or amendment to this Agreement, nor any waiver of any rights, will be effective unless assented to in writing by the Party to be charged, and the waiver of any breach or default will not constitute a waiver of any other right hereunder or any subsequent breach or default.

8.10 Counterparts. This Agreement may be executed in counterparts or duplicate originals, all of which shall be regarded as one and the same instrument, and which shall be the official and governing version in the interpretation of this Agreement. This Agreement may be executed by facsimile signatures or other electronic means and such signatures shall be deemed to bind each Party as if they were original signatures.

8.11 Notices. All notices and other communications required by this Agreement shall be in writing in the English language and shall be deemed given if delivered personally or by facsimile transmission (receipt verified), mailed by registered or certified mail (return receipt requested), postage prepaid, or sent by express courier service, to the Parties at the following addresses (or at such other addresses that a Party specifies by like notice; provided, however, that notices of a change of address shall be effective only upon written receipt thereof):

If to Baxalta, addressed to:

Shire Pharmaceuticals
300 Shire Way
Lexington, MA 02421
Attn: General Counsel

If to Xenetic, addressed to:

Xenetic Biosciences, Inc.
99 Hayden Ave
Suite 230
Lexington, MA 02421
Attn: Chief Executive Officer

[Signature Page Follows]

[***] Indicates portions of this exhibit that have been omitted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.

EXECUTION VERSION

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be signed below by their respective duly authorized officers.

On behalf of Xenetic Biosciences, Inc.

By: /s/ Jeffrey F. Eisenberg
Name: Jeffrey F. Eisenberg
Title: Chief Executive Officer
Date: October 27, 2017

On behalf of Baxalta Incorporated

By: /s/ Patrick S. Eagleman
Name: Patrick S. Eagleman
Title: Sr. Patent Counsel
Date: October 27, 2017

On behalf of Baxalta US Inc.

By: /s/ Patrick S. Eagleman
Name: Patrick S. Eagleman
Title: Sr. Patent Counsel
Date: October 27, 2017

On behalf of Baxalta GmbH

By: /s/ Patrick S. Eagleman
Name: Patrick S. Eagleman
Title: Sr. Patent Counsel
Date: October 27, 2017

[***] Indicates portions of this exhibit that have been omitted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.

EXECUTION VERSION

Exhibit A

Xenetic Patents

[***]

[***] Indicates portions of this exhibit that have been omitted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.

EXECUTION VERSION

Exhibit B

"Net Sales" shall be calculated in the same manner as [***] calculates Net Sales reported to its shareholders and means all gross revenues, recognized in accordance with the International Financial Reporting Standards from the sale of Licensed Product to Third Parties in the Territory, less the following deductions relating to such sales, to the extent actually incurred, allowed, or paid:

(i) cash discounts;

(ii) reasonable estimates for chargebacks, rebates, administrative fee arrangement and similar price concessions offered to wholesalers and other distributors, buying groups, health care insurance carriers, pharmacy benefit management companies, health maintenance organizations, other institutions or health care organizations, or other customers directly related to the sale of Licensed Product;

(iii) reasonable estimates for rebates or other price reductions provided, based on sales of Licensed Product to any governmental or regulatory authority in respect of state or federal Medicare, Medicaid or similar programs; and

(iv) two percent (2.0%) of gross revenues of Licensed Product to cover operating expenses such as warehousing, shipping, distribution, bad debt, record keeping, report preparation, insurance, freight, packing, and transportation.

Exhibit 10.47

Dated 2017

XENETIC BIOSCIENCES (UK) LIMITED
and
LIPOXEN TECHNOLOGIES LIMITED
and
XENETIC BIOSCIENCES INC.
and
MICHAEL SCOTT MAGUIRE

SETTLEMENT AGREEMENT

Without prejudice and subject to contract

TABLE OF CONTENTS

This Agreement is dated 2017.

Parties

(1) Xenetic Biosciences (UK) Limited incorporated and registered in England and Wales with company number 03213174 whose registered office is at 5th Floor, 15 Whitehall, London, SW1A 2DD (the **"Company"**);

(2) Lipoxen Technologies Limited incorporated and registered in England and Wales with company number 03401495 whose registered office is at 5th Floor, 15 Whitehall London SW1A 2DD ("**LTL**");

(3) Xenetic Biosciences Inc., a Nevada Corporation with a principal place of business at 99 Hayden Avenue, Suite 230, Lexington, MA 02421 ("**XBIO**");

(4) Michael Scott Maguire of 23 Palace Court, London, W2 4LP (the "**Employee**").

Background

(A) The Employee was appointed as CEO of Lipoxen Plc in March 2004, after which Lipoxen Plc acquired Lipoxen Technologies Limited ("**LTL**").

(B) In November 2009 the Employee entered into the Service Agreement.

(C) In 2011 Lipoxen Plc changed its name to Xenetic Biosciences Plc.

(D) Pursuant to a subsequent merger between Xenetic Biosciences Plc and Xenetic Biosciences, Inc., Xenetic Biosciences Plc was renamed Xenetic Biosciences (UK) Limited.

(E) The parties have agreed that the Employee's role of CEO ceased on 26 October 2017 and that thereafter he shall continue in employment with the Xenetic Group (with his employment transferring to Lipoxen Technologies Limited, an associated employer of the Company for the purposes of section 231 of the Employment Rights Act 1996) albeit in a new role (the **"New Role**"). The New Role will entail both a change in duties and a drop in earnings. In recognition of this change compensation as set out in this Agreement will be paid.

(F) The New Role involves advising the management and Board of Directors of XBIO on matters relating to the strategy, technology, operations and history of the Group. In particular, given the Executive's long history and relationships with Shire plc and its affiliates ("**Shire**") the Executive shall work with the CEO of XBIO to continue transitioning primary responsibility for, and point of contact with, Shire. Notwithstanding the foregoing, the Executive shall be reasonably available to address routine inquiries from Company management.

(G) Between the date of this Agreement and 31 October 2018 or such earlier date as agreed by the parties (the "**Termination Date**") the Employee will be employed by Lipoxen Technologies Limited in the New Role, the terms of which shall be set out in a new service agreement. Nothing in this Agreement shall prevent Lipoxen Technologies Limited from having the ability to terminate the Employee's employment immediately in the event that the Employee commits an act of gross misconduct.

(H) The parties have entered into this Agreement to record and implement the terms on which they have agreed to settle any claims which the Employee has or may have in connection with his employment as CEO or its termination against the Company or any Group Company (as defined below) or its or their officers or employees whether or not those claims are, or could be, in the contemplation of the parties at the time of signing this Agreement, and including, in particular, the statutory complaints which the Employee raises in this Agreement.

(I) The Employee and Xenetic Biosciences (UK) Limited, Lipoxen Technologies Limited, Xenetic Biosciences Inc. will enter into a Second Settlement Agreement on, or within 7 days after, the earlier of the Termination Date or such earlier date as the Employee's employment in the New Role terminates.

(J) The Company enters into this Agreement for itself and as agent and trustee for all Group Companies and it is authorised to do so. It is the parties' intention that each Group Company should be able to enforce any rights it has under this Agreement, subject to and in accordance with the Contracts (Rights of Third Parties) Act 1999.

(K) Nothing in this Agreement shall settle or compromise any claim the Employee may have against any person, entity or company which claim does not arise from or is part of the Xenetic Group of companies.

Agreed terms

1. Interpretation

The following definitions and rules of interpretation apply in this Agreement.

"Adviser"	Paul Seath of Bates Wells Braithwaite, 10 Queen Street Place, London EC4R 1BE.
"Board"	the board of directors of the Company (including any committee of the board appointed by it).
"Confidential Information"	information in whatever form (including, without limitation, in written, oral, visu electronic form or on any magnetic or optical disk or memory and wherever loc relating to the business, products, affairs and finances of the Company or any C Company for the time being confidential to the Company or any Group Compan trade secrets including, without limitation, technical data and know-how relating business of the Company or any Group Company or any of its or their suppliers, cl customers, agents, distributors, shareholders or management, including (but not li to) information that the Employee created, developed, received or obtained in conn with his employment, whether or not such information (if in anything other thai form) is marked confidential.

"Copies"	copies or records of any Confidential Information in whatever form (including, w limitation, in written, oral, visual or electronic form or on any magnetic or optical d memory and wherever located) including, without limitation, extracts, analysis, st plans, compilations or any other way of representing or recording and rec information which contains, reflects or is derived or generated from Confid Information.
"Group Company"	the Company, and any company in the Xenetic Group
"Service Agreement"	the contract between the entity formerly known as Lipoxen Plc and the Employee d November 2009.
"Xenetic Group	Xenetic Biosciences Inc. (the US parent company), Xenetic Bioscience Inc. (corporation being a wholly owned subsidiary of Xenetic Biosciences (UK) Lim Xenetic Biosciences (UK) Limited (a UK company being a wholly owned subsidi Xenetic Biosciences, Inc), Lipoxen Technologies Limited (a UK company being a w owned subsidiary of Xenetic Biosciences (UK) Limited) and SymbioTec Gmb German company being a wholly owned subsidiary of Xenetic Biosciences (UK) Li

1.1 The headings in this Agreement are inserted for convenience only and shall not affect its construction.

1.2 A reference to a particular law is a reference to it as it is in force for the time being taking account of any amendment, extension, or re-enactment and includes any subordinate legislation for the time being in force made under it.

1.3 Unless the context otherwise requires, a reference to one gender shall include a reference to the other genders.

1.4 Unless the context otherwise requires, words in the singular shall include the plural and in the plural shall include the singular.

1.5 The Schedules shall form part of this Agreement and shall have effect as if set out in full in the body of this Agreement. Any reference to this Agreement includes the Schedules.

1.6 References to any officers or employees of the Company or any member of the Xenetic Group is a reference to such officer or employee acting in their capacity as an officer or employee of such company and in no other capacity.

2. Arrangements until termination

2.1 The Employee's notice period shall commence on the date of this Agreement. The Employee's employment with the Company will therefore terminate on 31 October 2018 (the "**Termination Date**").

2.2 The Employee's role of Group CEO with the Company ended on 26 October 2017.

2.3 Regardless of whether or not the Employee enters into the Second Settlement Agreement referred to at clause 2.9 below, the Company shall pay the Employee his salary and contractual benefits up to the Termination Date in the usual way. For the avoidance of doubt, the Employee's contractual benefits are family private medical insurance, travel insurance, permanent health insurance, monthly health checks, family dental, life insurance, payment for US tax return advice (in respect of which the invoice for 2016 advice is outstanding and the invoice for 2017 is yet to be submitted).

2.3.1 The Company (and the Xenetic Group) shall continue to pay all premiums due in respect of any insurance in place to cover the benefits set out in clause 2.3 above.

2.3.2 The Company (and the Xenetic Group) shall make reasonable efforts to renew the insurance policy which currently underwrites the Employee's contractual entitlement to permanent health insurance. If having done so the Company (or the Xenetic Group) cannot renew that insurance policy the Employee's entitlement to permanent health insurance shall cease.

2.4 The Employee will submit his expense claims and the Company shall reimburse the Employee for any business expenses properly incurred on or before the Termination Date in the usual way.

2.5 The payments in this clause 2 are subject to the income tax and National Insurance contributions that the Company is obliged by law to pay or deduct.

2.6 Notwithstanding any terms of this Agreement, or the facts and circumstances referred to in this Agreement and regardless of whether or not the Employee enters into the Second Settlement Agreement referred to at clause 2.9 below, the Employee will continue to be entitled to the following:

(a) any share options which have been granted to him subject to the terms of the replacement incentive share option agreement entered into between (1) the Employee, (2) XBIO and (3) the Company dated 23 January 2014 (the "**UK Share Option Agreement**"); and

(b) any share options which have been granted to him subject to the rules of the XBIO equity incentive plan, effective 23 January 2014 (the "**2014 US Equity Incentive Plan**") (including but not limited to non-qualified options and unapproved options), and any such options granted under the 2014 US Equity Incentive Plan, and not yet vested at the date of this Agreement shall continue to vest during the Employee's notice period (referred to at clause 2.1 above) in accordance with the rules of the 2014 US Equity Incentive Plan.

2.7 The parties agree that the vesting of such options which have not vested as at the Termination Date shall be accelerated such that all unvested options under the UK Share Option Agreement and the 2014 US Equity Incentive Plan (collectively, the "**Option Agreements**") as at the Termination Date shall vest immediately and all vested options will be capable of exercise until 10 June 2020 (or such longer period, if any, as provided for in each respective Option Agreement).

2.8 For the avoidance of doubt and notwithstanding any terms of this Agreement, the parties acknowledge and agree that any other equity instruments held by or in favour of the Employee in respect of a Group Company (including, but not limited to, the Employee's JSOP and warrant entitlements) shall remain in full force and effect in accordance with the rules of such equity instrument.

2.9 Between the date of this Agreement and the Termination Date the Employee will be employed by LTL in the New Role, the terms of which are set out in a separate service agreement (the "**New Service Agreement**") and for the avoidance of doubt, the Employee will not be required to undertake any duties outside the scope of the New Role. Nothing in this Agreement shall prevent LTL from having the ability to terminate the Employee's employment immediately in the event that the Employee commits an act of gross misconduct.

2.10 On or within 7 days after the later of the Termination Date or such earlier date as the Employee's employment in the New Role terminates, the Employee will enter into the Second Settlement Agreement unless his employment terminates as a result of LTL's breach of contract.

2.11 The parties have entered into this Agreement to record and implement the terms on which they have agreed to settle any claims which the Employee has or may have in connection with his employment as CEO, including but not limited to those specified in Schedule 1 attached hereto.

2.12 Nothing in this Agreement or the New Service Agreement shall prevent the Employee from working for anyone else (or for himself) or being engaged, concerned or having any financial interest in any capacity in any other business, trade, profession or occupation during the term of the New Service Agreement. For the avoidance of doubt, this includes any non-executive board roles.

2.13 The Company shall settle any outstanding invoices the Employee has in respect of advice relating to his proposed move to Executive Chairman and his resignation as a Director of a Group Company.

3. Termination payment

3.1 Subject to any applicable conditions in clause 4 being met, the Company will, without admission of liability, pay the Employee as compensation in connection with the termination of his role as CEO £30,000 (the "**Termination Payment**") in one instalment. The Company will pay the Termination Payment by bank transfer to the Employee's normal bank account within five days of receipt by the Company of this Agreement signed by the Employee and certified by the Employee's Adviser.

3.2 The Company and the Employee believe that the Termination Payment can be paid tax-free. The Employee shall be responsible for any further tax and employee's National Insurance contributions due in respect of payments set out above and shall indemnify the Company in respect of such liability in accordance with clause 7.1.

4. Payment conditions

4.1 The payment under clause 3.1 of this Agreement is subject to the following conditions being met:

4.1.1 the Employee not having been in repudiatory breach of this Agreement;

4.1.2 the Employee hereby undertaking to enter into the Second Settlement Agreement and to provide the Company with the same signed by the Employee and certified by the Employee's Advisor.

5. Legal fees

The Company shall pay the reasonable legal fees (up to a maximum of £27,000 plus VAT including disbursements) incurred by the Employee in obtaining advice on the termination of his employment and the terms of this Agreement, such fees to be payable to the Adviser on production of an invoice addressed to the Employee (such fees to be payable to the Adviser within 21 days of production of an invoice) but marked as payable by the Company, The Adviser's fees shall be the only legal or professional fees reimbursable to the Employee or paid on behalf of the Employee by the Company under the Agreement (up to a maximum of £27,000 plus VAT).

6. Waiver of claims

6.1 Save as provided for under clauses 2.3, 2.6, 2.7, 2.8 or otherwise under this Agreement, the Employee agrees that the terms of this Agreement are offered by the Company without any admission of liability on the part of the Company and are in full and final settlement of all and any claims or rights of action that the Employee has or may have against the Company or any Group Company or its officers or employees whether arising out of his employment as CEO and director of XBIO and the Company or their termination, whether under common law, contract, statute or otherwise, whether such claims are, or could be, known to the parties or in their contemplation at the date of this Agreement in any jurisdiction and including, but not limited to, the claims specified in Schedule 1 (each of which is hereby intimated and waived).

6.2 The waiver in clause 6.1 shall not apply to the following:

6.2.1 any claims by the Employee to enforce this Agreement;

6.2.2 claims in respect of personal injury of which the Employee is not aware and could not reasonably be expected to be aware at the date of this Agreement;

6.2.3 any claims in relation to accrued pension entitlements;

6.2.4 any claims in relation to the Employee's rights as a shareholder in the Company and other Group Companies; and

6.2.5 any claims in relation to the Employee's contractual right to permanent health insurance so long as the current insurance policy (number G01669 / 9441 (effective from 21 June 2017)) or any renewal policy is in place.

6.3 The Employee warrants that:

6.3.1 before entering into this Agreement he received independent advice from the Adviser as to the terms and effect of this Agreement and, in particular, on its effect on his ability to pursue any complaint before an employment tribunal or other court;

6.3.2 the Adviser has confirmed to the Employee that they are a solicitor holding a current practising certificate and that there is in force a policy of insurance covering the risk of a claim by the Employee in respect of any loss arising in consequence of their advice;

6.3.3 the Adviser shall sign and deliver to the Company a letter in the form attached as Schedule 2 to this Agreement;

6.3.4 before receiving the advice the Employee disclosed to the Adviser all facts and circumstances that may give rise to a claim by the Employee against the Company or any Group Company;

6.3.5 the only claims that the Employee has or may have against the Company or any Group Company or its officers or employees (whether at the time of entering into this Agreement or in the future) relating to his employment with the Company or the termination of his role as CEO and as director of XBIO and the Company are specified in clause 6.1; and.

6.3.6 the Employee is not aware of any facts or circumstances that may give rise to any claim against the Company or any Group Company or any of its employees other than those claims specified in clause 6.1.

The Employee acknowledges that the Company acted in reliance on these warranties when entering into this Agreement.

6.4 The Employee acknowledges that the conditions relating to settlement agreements under section 147(3) of the Equality Act 2010, section 77(4A) of the Sex Discrimination Act 1975 (in relation to claims under that Act and the Equal Pay Act 1970), section 72(4A) of the Race Relations Act 1976, paragraph 2 of Schedule 3A to the Disability Discrimination Act 1995, paragraph 2(2) of Schedule 4 to the Employment Equality (Sexual Orientation) Regulations 2003, paragraph 2(2) of Schedule 4 to the Employment Equality (Religion or Belief) Regulations 2003, paragraph 2(2) of Schedule 5 to the Employment Equality (Age) Regulations 2006, section 288(2B) of the Trade Union and Labour Relations (Consolidation) Act 1992, section 203(3) of the Employment Rights Act 1996, regulation 35(3) of the Working Time Regulations 1998, section 49(4) of the National Minimum Wage Act 1998, regulation 41(4) of the Transnational Information and Consultation etc. Regulations 1999, regulation 9 of the Part-Time Workers (Prevention of Less Favourable Treatment) Regulations 2000, regulation 10 of the Fixed-Term Employees (Prevention of Less Favourable Treatment) Regulations 2002, regulation 40(4) of the Information and Consultation of Employees Regulations 2004, paragraph 13 of the Schedule to the Occupational and Personal Pension Schemes (Consultation by Employers and Miscellaneous Amendment) Regulations 2006, regulation 62 of the Companies (Cross Border Mergers) Regulations 2007 and section 58 of the Pensions Act 2008 have been satisfied.

6.5 The waiver in clause 6.1 shall have effect irrespective of whether or not, at the date of this Agreement, the Employee is or could be aware of such claims or have such claims in his express contemplation (including such claims of which the Employee becomes aware after the date of this Agreement in whole or in part as a result of new legislation or the development of common law or equity).

6.6 The Employee agrees that, except for the payments and benefits provided for in, referred to in, or excluded from this Agreement and the New Service Agreement governing the New Role, and subject to the waiver in clause 6.1, he shall not be eligible for any further payment from the Company or any Group Company relating to his employment or the termination of his role as CEO and as director of XBIO and the Company and without limitation to the generality of the foregoing, he expressly waives any right or claim that he has or may have to payment of bonuses, any benefit or award programme or grant of equity interest, or to any other benefit, payment or award he may have received had his role as CEO not terminated.

7. Indemnities

7.1 Save in respect of any payments arising out of clauses 7.3 to 7.6 below, the Employee shall indemnify the Company on a continuing basis in respect of any income tax or National Insurance contributions (save for employers' National Insurance contributions) due in respect of the payments and benefits in clause 3.1 (and any related interest, penalties, costs and expenses). The Company shall give the Employee reasonable notice of any demand for tax which may lead to liabilities on the Employee under this indemnity and shall provide him with reasonable access to any documentation he may reasonably require to dispute such a claim (provided that nothing in this clause shall prevent the Company from complying with its legal obligations with regard to HM Revenue and Customs or other competent body).

7.2 If the Employee is ever in repudiatory breach of this Agreement or pursues a claim against the Company or any Group Company in breach of this Agreement, he agrees to indemnify the Company for any losses suffered as a result thereof, including all reasonable legal and professional fees incurred.

7.3 The Company agrees and undertakes to pay to HMRC any late payment interest and penalties raised on the Company by H M Revenue & Customs as a consequence of the Company's late payment of income tax and NICs payable as a result of the Promissory Note and security agreement issued to the Employee in July 2016. It is recognised that the Employee has paid to the Employer all the income tax and employee national insurance payable by the Company in respect of the loan note.

7.4 The Company agrees to indemnify the Employee against one half of any income tax liability of the Employee under section 222 of the Income Tax (Earnings and Pensions) Act 2003 (“Section 222”) in relation to the Promissory Note and security agreement issued to the Employee in July 2016. In addition, the Company agrees to indemnify the Employee against one half of any employee National Insurance contributions arising as a result of Section 222.

7.5 In satisfaction of such indemnity the Company shall pay to the Employee, no later than 31 December 2017, a cash sum, net of income tax and National Insurance contributions, of an amount which is sufficient to enable the Employee to pay to HMRC (under self-assessment) one half of the amount of income tax due under Section 222. In relation to the Employee's National Insurance contributions liability arising as a result of Section 222, the Company will pay an additional cash sum, net of income tax and National Insurance contributions, of an amount which is sufficient to cover one half of the Employee's NIC liability as a result of Section 222. This payment will be made at the same time that the earnings for NIC purposes are processed through the payroll system, included in a payslip and reported to HMRC.

7.6 The Employee shall, no later than 1 February 2018, confirm to the Company that he has included the Section 222 amount in his self-assessment tax return for the year to 5 April 2017. The Employee will inform the Company if he makes any submission or claim to HMRC that the Section 222 amount is lower than the amount to be reported by the Company on a revised form P11D for the year to 5 April 2017. If the Employee makes such a submission or claim then the Employee will be required to account to the Company in relation to half of the consequent reduction in the indemnity provided for in clause 7.4.

8. Company property and information

8.1 The Employee shall, before the Termination Date, return to the Company :

8.1.1 all Confidential Information and Copies;

8.1.2 all property belonging to the Company in satisfactory condition including (but not limited to) any company credit card, keys, security pass, identity badge, mobile telephone, pager, lap-top computer or fax machine but not his laptop, which he purchased; and

8.1.3 all documents and copies (whether written, printed, electronic, recorded or otherwise and wherever located) made, compiled or acquired by him during his employment with the Company or relating to the business or affairs of the Company or any Group Company or their business contacts

in the Employee's possession or under his control.

8.2 The Employee shall, before the Termination Date, erase irretrievably any information relating to the business or affairs of the Company or any Group Company or its business contacts from computer and communications systems and devices owned or used by him outside the premises of the Company, including such systems and data storage services provided by third parties (to the extent technically practicable).

8.3 The Employee shall, if requested to do so by the Company or Board, provide a signed statement that he has complied fully with his obligations under clause 8.1 and clause 8.2 and shall provide it with such reasonable evidence of compliance as may be requested.

8.4 The Company shall procure that the Employee's mobile telephone number shall be transferred into his name as soon as possible after the date of this Agreement and in any event by the Termination Date.

9. Employee warranties and acknowledgments

9.1 As at the date of this Agreement, the Employee warrants and represents to the Company that there are no circumstances of which the Employee is aware or of which the Employee ought reasonably to be aware which would amount to a repudiatory breach by the Employee of any express or implied term of the Employee's Service Agreement which would entitle (or would have entitled) the Company to terminate the Employee's employment without notice or payment in lieu of notice and any payment to the Employee pursuant to clause 3 is conditional on this being so.

9.2 The Employee agrees to make himself available to, and to cooperate with, the Company or its advisers in any internal investigation or administrative, regulatory, judicial or quasi-judicial proceedings. The Employee acknowledges that this could involve, but is not limited to, responding to or defending any regulatory or legal process, providing information in relation to any such process, preparing witness statements and giving evidence in person on behalf of the Company. The Company shall reimburse any reasonable expenses and/or lost income incurred by the Employee as a consequence of complying with his obligations under this clause, provided that such expenses are approved in advance by the Company.

9.3 The Employee acknowledges that he is not entitled to any compensation for the loss of any rights or benefits under any share option, bonus, long-term incentive plan or other profit sharing scheme operated by the Company or any Group Company in which he may have participated, other than the payments referred to in clauses 2 and 3.

10. Resignation from offices

10.1 The Employee acknowledges that, with effect from 26 October 2017, he has resigned from his positon as CEO of the Company.

10.2 The Employee irrevocably appoints the Company to be his attorney in his name and on his behalf to sign, execute or do any such instrument or thing and generally to use his name in order to give the Company (or its nominee) the full benefit of the provisions of this clause.

11. Confidentiality, announcements and reference

11.1 The Employee acknowledges that, as a result of his employment as CEO and his continued employment with LTL he has had (and will have) access to Confidential Information. Without prejudice to his common law duties, the Employee shall not (except as authorised or required by law or as authorised by the Company) at any time after the Termination Date:

11.1.1 use any Confidential Information; or

11.1.2 make or use any Copies; or

11.1.3 disclose any Confidential Information to any person, company or other organisation whatsoever.

11.2 The restrictions in clause 11.1 do not apply to any Confidential Information which is in or comes into the public domain other than through the Employee's unauthorised disclosure.

11.3 Subject to clause 11.6, the Employee and the Company confirm that they have kept and agree to keep the existence and terms of this Agreement and the circumstances concerning the termination of the Employee's role as CEO confidential, save where such disclosure is to HM Revenue & Customs, required by law or (where necessary or appropriate) to:

11.3.1 the Employee's spouse, civil partner or partner, immediate family or legal or professional advisers, provided that they agree to keep the information confidential; or

11.3.2 the Employee's insurer for the purposes of processing a claim for loss of employment.

11.4 The Company may also disclose the existence and terms of this Agreement to the Company's officers, employees or legal or professional advisers on a need to know basis, provided that they agree to keep the information confidential.

11.5 The Company may make an announcement on signature of this Agreement in the form set out in Schedule 4 and neither party will make any statement to third parties (save as specified in clauses 11.3 and 11.6) which is inconsistent with that announcement.

11.6 Subject to clause 11.7, the Company or any Group Company may make such announcements and disclosures about the Employee resigning as CEO and the terms set out in this Agreement as required by US regulatory requirements.

11.7 Save as in pursuance of any legitimate legal action (including pre-action) the Employee shall not make any adverse or derogatory comment about any Group Company, its or their officers or employees and all Group Companies shall use reasonable endeavours to ensure that its or their employees and officers shall not make any adverse or derogatory comment about the Employee. The Employee shall not do anything which shall, or may, bring any Group Company, its or their officers or employees into disrepute and all Group Companies shall use reasonable endeavours to ensure that its employees and officers shall not do anything which shall, or may, bring the Employee into disrepute.

11.8 Nothing in this clause 11 shall prevent the Employee from making a protected disclosure under section 43A of the Employment Rights Act 1996 and nothing in this clause 11 shall prevent the Company from making such disclosure as it is required by law to make. Notwithstanding the foregoing, the Employee and the Company mutually warrant that neither is currently aware of any grounds which would justify a protected disclosure.

11.9 On signature of this Agreement and on receipt of a written request from a potential employer, the Company shall provide a reference in the form set out in Schedule 5 to this Agreement and any oral reference provided will be on no less favourable terms.

12. Directors Liability Insurance

12.1 The Company warrants that it has and will continue to maintain directors' liability insurance covering the Company and any Group Company.

13. Guarantee

13.1 XBIO shall guarantee all payments, benefits and indemnities under this Agreement (including but not limited to those provided under clauses 2.3 and 7.3, 7.4 and 7.5) and shall pay them as they fall due if the Company does not.

14. Entire agreement

14.1 Each party on behalf of itself and, in the case of the Company, as agent for any Group Companies acknowledges and agrees with the other party (the Company acting on behalf of itself and as agent for each Group Company) that:

14.1.1 this Agreement and any document referred to in it constitutes the entire agreement between the parties and any Group Company and supersedes and extinguishes all agreements, promises, assurances, warranties, representations and understandings between them whether written or oral, relating to its subject matter;

14.1.2 in entering into this Agreement it does not rely on , and shall have no remedies in respect of, any statement, representation, assurance or warranty (whether made innocently or negligently) that is not set out in this Agreement; and

14.1.3 it shall have no claim for innocent or negligent misrepresentation based on any statement in this Agreement.

14.2 Nothing in this Agreement shall, however, operate to limit or exclude any liability for fraud.

15. Variation

No variation of this Agreement shall be effective unless it is in writing and signed by the parties (or their authorised representatives).

16. Third party rights

16.1 Any third party shall be entitled to enforce the benefits conferred on it by clauses 6, 8, 11 and 12 of this Agreement.

16.2 Except as expressly provided in clause 15.1, no person other than the Employee and the Company or any Group Company shall have any rights under the Contracts (Rights of Third Parties) Act 1999 to enforce any term of this Agreement. This does not affect any right or remedy of a third party which exists, or is available, apart from that Act.

17. Governing law

This Agreement and any dispute or claim arising out of or in connection with it or its subject matter or formation (including non-contractual disputes or claims) shall be governed by and construed in accordance with the law of England and Wales.

18. Jurisdiction

Each party irrevocably agrees that the courts of England and Wales shall have exclusive jurisdiction to settle any dispute, claim arising out of or in connection with this Agreement or its subject matter or formation (including non-contractual disputes or claims).

19. Subject to contract and without prejudice

This Agreement shall be deemed to be without prejudice and subject to contract until such time as it is signed by both parties and dated, when it shall be treated as an open document evidencing a binding agreement.

20. Counterparts

This Agreement may be executed and delivered in any number of counterparts, each of which, when executed, shall constitute a duplicate, but all the counterparts shall together constitute the one agreement.

Schedule 1
Claims

1.1 for breach of contract or wrongful dismissal;

1.2 for unfair dismissal, under section 111 of the Employment Rights Act 1996;

1.3 in relation to the right to a written statement of reasons for dismissal, under section 93 of the Employment Rights Act 1996;

1.4 for a statutory redundancy payment, under section 163 of the Employment Rights Act 1996;

1.5 in relation to an unlawful deduction from wages or unlawful payment, under section 23 of the Employment Rights Act 1996;

1.6 for unlawful detriment, under section 48 of the Employment Rights Act 1996 or section 56 of the Pensions Act 2008;

1.7 in relation to written employment particulars and itemised pay statements, under section 11 of the Employment Rights Act 1996;

1.8 in relation to guarantee payments, under section 34 of the Employment Rights Act 1996;

1.9 in relation to suspension from work, under section 70 of the Employment Rights Act 1996;

1.10 in relation to parental leave, under section 80 of the Employment Rights Act 1996;

1.11 in relation to a request for flexible working, under section 80H of the Employment Rights Act 1996;

1.12 in relation to time off work, under sections 51, 54, 57, 57B, 60, 63 and 63C of the Employment Rights Act 1996;

1.13 in relation to working time or holiday pay, under regulation 30 of the Working Time Regulations 1998;

1.14 for direct or indirect discrimination, harassment or victimisation related to sex, marital or civil partnership status, pregnancy or maternity or gender reassignment under section 120 of the Equality Act 2010 and/or direct or indirect discrimination, harassment or victimisation related to sex, marital or civil partnership status, gender reassignment, pregnancy or maternity under section 63 of the Sex Discrimination Act 1975;

1.15 for direct or indirect discrimination, harassment or victimisation related to race under section 120 of the Equality Act 2010;

1.16 for direct or indirect discrimination, harassment or victimisation related to disability, discrimination arising from disability, or failure to make adjustments under section 120 of the Equality Act 2010 and/or direct discrimination, harassment or victimisation related to disability, disability-related discrimination or failure to make adjustments under section 17A of the Disability Discrimination Act 1995;

1.17 for direct or indirect discrimination, harassment or victimisation related to religion or belief under section 120 of the Equality Act 2010 and/or under regulation 28 of the Employment Equality (Religion or Belief) Regulations 2003;

1.18 for direct or indirect discrimination, harassment or victimisation related to sexual orientation, under section 120 of the Equality Act 2010 and/or under regulation 28 of the Employment Equality (Sexual Orientation) Regulations 2003;

1.19 for direct or indirect discrimination, harassment or victimisation related to age, under section 120 of the Equality Act 2010 and/or under regulation 36 of the Employment Equality (Age) Regulations 2006;

1.20 in relation to the duty to consider working beyond retirement, under paragraphs 11 and 12 of Schedule 6 to the Employment Equality (Age) Regulations 2006;

1.21 for less favourable treatment on the grounds of part-time status, under regulation 8 of the Part-Time Workers (Prevention of Less Favourable Treatment) Regulations 2000;

1.22 under regulations 27 and 32 of the Transnational Information and Consultation etc. Regulations 1999;

1.23 under regulations 29 and 33 of the Information and Consultation of Employees Regulations 2004;

1.24 under regulations 45 and 51 of the Companies (Cross-Border Mergers) Regulations 2007;

1.25 under paragraphs 4 and 8 of the Schedule to the Occupational and Personal Pension Schemes (Consultation by Employers and Miscellaneous Amendment) Regulations 2006;

1.26 under sections 68A, 87, 137, 145A, 145B, 146, 168, 168A, 169, 170, 174 and 192 of the Trade Union and Labour Relations (Consolidation) Act 1992;

1.27 in relation to the obligations to elect appropriate representatives or any entitlement to compensation, under the Transfer of Undertakings (Protection of Employment) Regulations 2006;

1.28 in relation to the right to be accompanied under section 11 of the Employment Relations Act 1999;

1.29 in relation to refusal of employment, refusal of employment agency services and detriment under regulations 5, 6 and 9 of the Employment Relations Act 1999 (Blacklists) Regulations 2010;

1.30 in relation to the right to request time off for study or training under section 63I of the Employment Rights Act 1996; and

1.31 in relation to personal injury, which the Employee is aware of or ought reasonably to be aware of at the date of this Agreement;

1.32 for harassment under the Protection from Harassment Act 1997;

1.33 for failure to comply with obligations under the Human Rights Act 1998;

1.34 for failure to comply with obligations under the Data Protection Act 1998; and

1.35 arising as a consequence of the United Kingdom's membership of the European Union.

Dear Sirs,

I am writing in connection with the agreement between my client, Scott Maguire, and XENETIC BIOSCIENCES (UK) LIMITED, LIPOXEN TECHNOLOGIES LIMITED, and XENETIC BIOSCIENCES INC. of today's date to confirm that:

1. I, Paul Seath of Bates Wells Braithwaite, whose address is 10 Queen Street Place, London, EC4R 1BE, am a Solicitor of the Senior Courts of England and Wales who holds a current practising certificate.

2. I have given Scott Maguire legal advice on the terms and effect of the Agreement and, in particular, its effect on his ability to pursue the claims specified in *Schedule 1* of the Agreement.

3. I gave the advice to Scott Maguire as a relevant independent adviser within the meaning of the above acts and regulations referred to at clause 6.4.

4. There is now in force (and was in force at the time I gave the advice referred to above) a policy of insurance or an indemnity provided for members of a profession or professional body covering the risk of claim by Scott Maguire in respect of loss arising in consequence of the advice I have given him.

Yours faithfully,

Paul Seath

/s/ Paul Seath

November 2017

Schedule 2
Adviser's certificate

[DATE]

Dear Sirs,

I am writing in connection with the agreement between my client, Scott Maguire, and XENETIC BIOSCIENCES (UK) LIMITED, LIPOXEN TECHNOLOGIES LIMITED, and XENETIC BIOSCIENCES INC. of today's date to confirm that:

1. I, Paul Seath of Bates Wells Braithwaite, whose address is 10 Queen Street Place, London, EC4R 1BE, am a Solicitor of the Senior Courts of England and Wales who holds a current practising certificate.

2. I have given Scott Maguire legal advice on the terms and effect of the Agreement and, in particular, its effect on his ability to pursue the claims specified in *Schedule 1* of the Agreement.

3. I gave the advice to Scott Maguire as a relevant independent adviser within the meaning of the above acts and regulations referred to at *clause 6.4*.

4. There is now in force (and was in force at the time I gave the advice referred to above) a policy of insurance or an indemnity provided for members of a profession or professional body covering the risk of claim by Scott Maguire in respect of loss arising in consequence of the advice I have given him.

Yours faithfully,

Paul Seath

[ ] October 2017

Schedule 3
Second Settlement Agreement

Without prejudice and subject to contract

This Agreement is made on …….between Xenetic Biosciences (UK) Limited (the "Company"), Lipoxen Technologies Limited ("LTL"), Xenetic Biosciences Inc. ("XBIO") and Michael Scott Maguire (the "Employee").

Background

A. The Company and the Employee have already entered into a settlement agreement dated [ ] ("the First Settlement Agreement"). It is a term of the First Settlement Agreement that the parties enter into a second settlement agreement at the date the Employee's employment terminates to confirm that the Employee waives any additional claims that he might have against the Company or any Third Party.

B. All the terms of the First Settlement Agreement continue to apply and remain in force. They are not superseded by the terms of this Agreement. Furthermore, all defined terms have the same meaning when used in this Agreement as in the First Settlement Agreement.

1. Payment

1.1 Subject to the terms and conditions set out in the First Settlement Agreement, the Company will make the payments set out therein.

2. Settlement

2.1 Save as provided for under clauses 2.3, 2.6, 2.7, 2.8 and 6.2 of the First Settlement Agreement or otherwise provided for under the First Settlement Agreement, (or in respect of any valid claim which may be made under any PHI insurance policy) the Employee agrees that the terms of this Agreement are offered by the Company without any admission of liability on the part of the Company and are in full and final settlement of all and any claims or rights of action that the Employee has or may have against the Company, LTL, XBIO or any Group Company or its officers or employees whether arising out of his employment with the Company or LTL or its termination or otherwise from events occurring after the First Settlement Agreement was entered into, whether under common law, contract, statute or otherwise, whether such claims are, or could be, known to the parties or in their contemplation at the date of this Agreement in any jurisdiction and including, but not limited to, the claims specified in Schedule 1 to the First Settlement Agreement (each of which is hereby intimated and waived).

2.2 Clause 2.1 above applies to all present and future claims, costs, expenses or rights of action save in relation to any excluded matters and the matters referred to in clause 6.2 of the First Settlement Agreement above and shall have effect irrespective of whether or not the Employee is or could be aware of such claims, costs, expenses or rights of action at the date of this Agreement and irrespective of whether such claims, costs, expenses or rights of action are in the express contemplation of the Company, LTL, XBIO and the Employee at the date of this Agreement (including such claims of which the Employee becomes aware after the date of this Agreement in whole or in part as a result of new legislation or the development of common law or equity).

2.3 The Employee hereby warrants that:

2.3.1 He is not aware of any facts or circumstances which might give rise to a claim against the Company, LTL, XBIO or any Group Company or its or their officers or employees other than those set out in clause 2.1 or otherwise in the First Settlement Agreement; and

2.3.2 He has not and will not commence any legal or arbitration proceedings of any nature against the Company, LTL or any Group Company in any jurisdiction arising out of or in connection with his employment with the Company or LTL, its termination or otherwise save for the purposes of enforcing the terms of the First Settlement Agreement or this Agreement or in respect of claims excluded by either Agreement.

2.4 It is expressly agreed that, except as expressly provided for in, referred to in, or excluded from this Agreement and the First Settlement Agreement the Company, LTL and any Group Company shall have no further obligation to the Employee and the Employee shall have no further entitlement under the Service Agreement and the New Service Agreement.

3. Continuing obligations

3.1 For the avoidance of doubt, the Employee confirms that clauses 11 and 12 of the First Settlement Agreement remain in full force and effect notwithstanding the execution of this Agreement.

4. Warranties

4.1 The Employee hereby warrants that he:

4.1.1 Has not at any time committed a repudiatory breach of his contract of employment which would entitle LTL to terminate his employment without notice;

4.1.2 Is not entering into this Agreement in reliance on any undertaking, representation, warranty or arrangement of any nature not expressly set out in this agreement; and

4.1.3 Has not disclosed or communicated to any person the circumstances surrounding the termination of his employment with the Company or LTL and the facts or terms of this Agreement or the First Settlement Agreement, except to his legal and professional advisers.

5. Legal advice

5.1 The Employee has received advice from Paul Seath of Bates Wells Braithwaite, 10 Queen Street Place, London EC4R 1BE, a relevant independent adviser for the purposes of section 203 of the Employment Rights Act 1996, as to the terms and effect of this Agreement and, in particular, its effect on his ability to pursue any complaint before an employment tribunal or other court.

5.2 The Employee acknowledges that the conditions relating to settlement agreements under section 147(3) of the Equality Act 2010, section 77(4A) of the Sex Discrimination Act 1975 (in relation to claims under that Act and the Equal Pay Act 1970), section 72(4A) of the Race Relations Act 1976, paragraph 2 of Schedule 3A to the Disability Discrimination Act 1995, paragraph 2(2) of Schedule 4 to the Employment Equality (Sexual Orientation) Regulations 2003, paragraph 2(2) of Schedule 4 to the Employment Equality (Religion or Belief) Regulations 2003, paragraph 2(2) of Schedule 5 to the Employment Equality (Age) Regulations 2006, section 288(2B) of the Trade Union and Labour Relations (Consolidation) Act 1992, section 203(3) of the Employment Rights Act 1996, regulation 35(3) of the Working Time Regulations 1998, section 49(4) of the National Minimum Wage Act 1998, regulation 41(4) of the Transnational Information and Consultation etc. Regulations 1999, regulation 9 of the Part-Time Workers (Prevention of Less Favourable Treatment) Regulations 2000, regulation 10 of the Fixed-Term Employees (Prevention of Less Favourable Treatment) Regulations 2002, regulation 40(4) of the Information and Consultation of Employees Regulations 2004, paragraph 13 of the Schedule to the Occupational and Personal Pension Schemes (Consultation by Employers and Miscellaneous Amendment) Regulations 2006, regulation 62 of the Companies (Cross Border Mergers) Regulations 2007 and section 58 of the Pensions Act 2008 have been satisfied.

5.3 Paul Seath's signature at the end of this Agreement confirms to the Company and LTL that, to the best of his knowledge and belief, the statements set out in clauses 5.2 and 5.3 of this Agreement are correct.

6. Legal Fees

6.1 The Company agrees to pay reasonable legal fees incurred by the Employee in connection with taking advice on the termination of his employment and the terms of this Agreement up to a maximum of £375 plus VAT to be paid direct to the Employee's solicitor 28 days after the receipt from the Employee's solicitor of an invoice addressed to the Employee and marked payable by LTL.

7. Third parties

7.1 Any third party shall be entitled to enforce the benefits conferred on it by clauses 2 and 3 of this Agreement.

7.2 Except as expressly provided in clause 6.1, no person other than the Employee and the Company, LTL or any Group Company shall have any rights under the Contracts (Rights of Third Parties) Act 1999 to enforce any term of this Agreement. This does not affect any right or remedy of a third party which exists, or is available, apart from that Act.

8. Governing law

8.1 This Agreement and any dispute or claim arising out of or in connection with it or its subject matter or formation (including non-contractual disputes or claims) shall be governed by and construed in accordance with the law of England and Wales.

9. Jurisdiction

9.1 Each party irrevocably agrees that the courts of England and Wales shall have exclusive jurisdiction to settle any dispute or claim arising out of or in connection with this Agreement or its subject matter or formation (including non-contractual disputes or claims).

10. Counterparts

10.1 This Agreement may be executed in any number of counterparts, each of which, when executed, shall constitute a duplicate and be an original, but all the counterparts shall together constitutes the one agreement.

This Agreement, although marked “without prejudice” and “subject to contract”, will upon signature by the parties and the adviser, be treated as an open document evidencing an agreement binding on the parties.

Signed…….

Dated……...

on behalf of the Company

Signed…….

Dated……...

on behalf of LTL

Signed…….

Dated……...

on behalf of XBIO

Signed……

Dated…….

Scott Maguire

Signed……

Dated…….

Paul Seath of Bates Wells Braithwaite

Schedule 4
Announcement

CONFIDENTIAL DRAFT NOT FOR IMMEDIATE RELEASE

Xenetic Biosciences Appoints Jeffrey F. Eisenberg as Chief Executive Officer

LEXINGTON, MA – (October 31, 2017) – Xenetic Biosciences, Inc. (NASDAQ: XBIO) ("Xenetic" or the "Company"), a clinical-stage biopharmaceutical company focused on the discovery, research and development of next-generation biologic drugs and novel orphan oncology therapeutics, announced today that it has appointed Jeffrey F. Eisenberg as Chief Executive Officer. M. Scott Maguire will continue to serve Xenetic during the management transition.

"On behalf of everyone at Xenetic, we would like to thank Scott for his years of commitment and dedication to the Company. Mr. Maguire joined a company with a collection of patents and transformed the Company into a clinical-stage business, listing the company on NASDAQ last year. His efforts were critical in securing an exclusive license deal with, and a series of equity investments from, Shire plc (LSE: SHP, NASDAQ: SHPG) (formerly Baxalta, Baxter Incorporated and Baxter Healthcare) to develop a novel series of polysialylated blood coagulation factors employing Xenetic's proprietary PolyXen™ technology platform," commented Adam Logal, Chairman of the Board of Xenetic. "We believe that Jeff's appointment today as Chief Executive Officer is an important step in the continued evolution of Xenetic. His industry experience and professional track record are perfectly aligned with the Company's strategic priorities, and I believe he will do a tremendous job leading the Xenetic team and driving the Company to its next phase of growth."

Mr. Eisenberg joined the Xenetic management team in December 2016 as Chief Operating Officer and has served on the Company's Board of Directors since July 2016. He is a seasoned life science executive with over 20 years of broad operational expertise. Over the course of his career, Mr. Eisenberg has led all crucial areas of R&D, operations, manufacturing/quality, business development, strategic partnering, product development, commercialization, and talent management. Prior to joining Xenetic, his most recent position was Chief Executive Officer of Noven Pharmaceuticals, where during his tenure as CEO revenues more than doubled, the company's cash increased by more than 300%, and two new products were launched following the successful filings of New Drug Applications (NDAs) submitted to the U.S. Food and Drug Administration. Mr. Eisenberg also was responsible for leading Noven's Novogyne joint venture with Novartis (NYSE: NVS), an entity that generated over $300 million in revenue in its last full year of operation.

Mr. Eisenberg commented, "I am very pleased to be appointed to lead Xenetic at this pivotal point in the Company's history, and I am prepared for this exciting challenge. We have a strong team in place, and together we will focus on continuing to fundamentally transform Xenetic on multiple fronts. We look forward to advancing our ongoing Phase 2 study of our flagship product, XBIO-101 as candidate for the treatment of progestin resistant endometrial cancer and announcing interim data from the study in 2018. Beyond XBIO-101, we believe there is an opportunity to build a growing pipeline of partnerships utilizing our proven PolyXen™ platform technology."

About Xenetic Biosciences

Xenetic Biosciences, Inc. is a clinical-stage biopharmaceutical company focused on the discovery, research and development of next-generation biologic drugs and novel orphan oncology therapeutics. Xenetic's lead investigational product candidate is oncology therapeutic XBIO-101 (sodium cridanimod) for the treatment of progesterone resistant endometrial cancer. Xenetic's proprietary drug development platforms include PolyXen, which enables next-generation biologic drugs by improving their half-life and other pharmacological properties.

Xenetic is party to an agreement with Baxalta US Inc. and Baxalta AB (wholly owned subsidiaries of Shire plc) covering the development of a novel series of polysialylated blood coagulation factors. This collaboration relies on Xenetic's PolyXen technology to conjugate polysialic acid ("PSA") to therapeutic blood-clotting factors, with the goal of improving the pharmacokinetic profile and extending the active life of these biologic molecules. Shire is a significant stockholder of the Company, having invested $10 million in the Company during 2014. The agreement is an exclusive research, development and license agreement which grants Shire a worldwide, exclusive, royalty-bearing license to Xenetic's PSA patented and proprietary technology in combination with Shire's proprietary molecules designed for the treatment of blood and bleeding disorders. The first program under this agreement was a next generation Factor VIII, and this program was terminated by Shire following a Phase 1/2 clinical trial. Xenetic and Shire are currently exploring whether to engage in further development of other blood coagulation factors. Additionally, Xenetic has previously received strategic investments from OPKO Health (Nasdaq: OPK), Serum Institute of India Limited and PJSC Pharmsynthez.

For more information, please visit the Company's website at www.xeneticbio.com and connect on Twitter, LinkedIn, Facebook and Google+.

Forward-Looking Statements

This press release contains forward-looking statements for purposes of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release other than statements of historical facts may constitute forward-looking statements within the meaning of the federal securities laws. These statements can be identified by words such as "expects," "plans," "projects," "will," "may," "anticipates," "believes," "should," "intends," "estimates," and other words of similar meaning, including statements regarding changes to the proposals included in the Company's proxy statement and the Company's plans to amend or supplement its proxy statement. Any forward-looking statements contained herein are based on current expectations, and are subject to a number of risks and uncertainties. Many factors could cause our actual activities or results to differ materially from the activities and results anticipated in forward-looking statements. These risks and uncertainties include those described in the "Risk Factors" section of the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2016 and filed with the Securities and Exchange Commission on March 31, 2017, and subsequent reports that it may file with the Securities and Exchange Commission. In addition, forward-looking statements may also be adversely affected by general market factors, competitive product development, product availability, federal and state regulations and legislation, the regulatory process for new product candidates and indications, manufacturing issues that may arise, patent positions and litigation, among other factors. The forward-looking statements contained in this press release speak only as of the date the statements were made, and the Company does not undertake any obligation to update forward-looking statements, except as required by law.

Contact:

Jenene Thomas Communications, LLC.
Jenene Thomas
(908) 938-1475
jenene@jenenethomascommunications.com

Source: Xenetic Biosciences, Inc.

Schedule 5
Reference

[ON HEADED NOTEPAPER OF XENETIC BIOSCIENCES, INC.]

To Whom It May Concern:

This is to confirm M. Scott Maguire has been employed as the CEO of Xenetic Biosciences Inc. (ticker: XBIO) since March 2004. During his tenure, Scott transformed the company from a collection of patents to a clinical-stage NASDAQ listed company.

- A list of a few of his notable accomplishments include:
- Listing on AIM within two years of being appointed CEO
- Moving projects from the bench into the clinic
- Raising capital from India, Russia, Europe and the US
- Completed a number of M&A transactions, including the acquisition of a German orphan oncology company and an oncology asset acquisition
- Securing a $100M license deal from Baxter (now Shire)
- Securing a series of investments from Shire
- Moving the company from London, UK to Boston, MA
- Listing the company on NASDAQ

We would give him the highest recommendation for future employment in an executive or non-executive capacity.

Sincerely yours

The Board of Directors of Xenetic Biosciences Inc.

This Agreement was executed as a deed on the date stated at the beginning of it.

Executed as a deed for and
on behalf of **Xenetic Biosciences (UK)**
Limited in the presence of

/s/ Colin Hill
Director

Witness

/s/ Victoria Exley
Signature

Victoria Exley
Name

Wayside Cottage, Euford SN96DD
Address

Solicitor
Occupation

Executed as a deed for and
on behalf of **LIPOXEN TECHNOLOGIES**
LIMITED in the presence of

/s/ Colin Hill
Director

Witness

/s/ Victoria Exley
Signature

Victoria Exley
Name

Wayside Cottage, Euford SN96DD
Address

Solicitor
Occupation

Signed by Scott Maguire

/s/ Scott Maguire

Witness

/s/ Stefano Caupolini
Signature

Stefano Caupolini
Name

19 Donne Place, London SW32N6
Address

Entrepreneur
Occupation

Executed as a deed for and on
behalf of **XENETIC BIOSCIENCES INC.** in the presence of

JEFFREY EISENBERG
Director

Witness

/s/ Dionne Smith
Signature

Dionne Smith
Name

4400 Biscayne Blvd.
Miami, FL 33137
Address

Executive Assistant
Occupation

Exhibit 10.48

Xenetic Bioscience, Inc.
99 Hayden Avenue, Suite 230
Lexington, MA 02421
p 781-778-7720
e info@xeneticbio.com

October 11, 2017

Adam Logal
Opko
4400 Biscayne Blvd.
Miami, Florida 33129

Dear Adam:
This Letter Agreement (the "Agreement") is to confirm the terms of your proposed appointment on August 14, 2017 (the "Effective Date") as a non-employee, independent Director of Xenetic Biosciences, Inc. (the "Company").

Overall, in terms of time commitment, we expect your attendance at all the Board meetings and meetings of such committees of the Board that you will be appointed to (as applicable). In addition, you will be expected to devote appropriate preparation time ahead of each meeting. By accepting this appointment, you have confirmed that you are able to allocate sufficient time to meet the expectations of this position.

1. Consideration. For and in consideration of the services to be performed by you, the Company agrees to compensate you as follows:

1.1 Director Fee. A director fee equal to $50,000 (Fifty Thousand U.S. Dollars) per annum, payable quarterly (the "Board Meeting Fee") will be the cash compensation for your role as a director, as well as any board committees, as chair or as a member, you may participate.

1.2 Stock Options. Subject to all approvals required by law, the Company will grant you, pursuant to an equity incentive plan or such other plan to be adopted by the Company (the "Plan") and upon such terms and conditions as determined by the Compensation Committee or the Board (as applicable), an option to purchase Twenty-Five Thousand (25,000) shares of common stock of the Company at a strike price determined by the closing price of the common stock on the date of this Agreement (the "Initial Grant"). This option shall be exercisable as provided herein and shall vest quarterly over twelve months so long as you are a member of our board of directors. An additional option to purchase 25,000 shares of Company common stock shall be granted for service each year at the date of the Company's Annual Meeting of Shareholders commencing with the 2018 Annual Meeting of Shareholders. The exercise price shall be determined by the closing price of the common stock on the date of such grant.

If your board service is terminated or ends for any reason, all granted Options that have not vested – shall be forfeited, and any Options that have vested but have not been exercised may be exercisable by you any time within three (3) months of the termination of your board position (the "Termination Exercise Period"). Any Options that are not exercised within the Termination Exercise Period, shall expire immediately.

1.2.1 Term of Options. All Options, if and to the extent vested according to Section 1.2 above, shall be in effect for a period of 10 years commencing immediately after the granting of all Options granted to you under this letter of appointment, and shall expire immediately thereafter, unless terminated sooner as provided in Section 1.2. Without derogating from the aforesaid, if the Plan that shall be approved by the Company shall include additional provisions related to expiration of Options, such provisions shall also apply with respect to all Options granted to you under this letter of appointment.

1.2.1a Vesting. All Options granted to you shall vest as provided in Section 1.2.

1.2.1b Price. The exercise price of the Options shall be equal to the Company's closing stock price on the date of your grant.

1.2.1c General. All options granted to you shall be in effect subject to your continuous service as a Director and subject to the terms and conditions of the Company's Stock Option Plan (the "Plan"), including such terms related to vesting and expiration, and subject to such terms and conditions as will be approved by the Company, at its sole discretion. In case of contradiction between the provisions of this letter of appointment and the provisions of the Plan, the provisions of the Plan shall supersede.

1.2.1d Certain Representations. You represent and agree that you are accepting the option to purchase shares of common stock being issued to you pursuant to this Agreement for your own account and not with a view to or for sale of distribution thereof. You understand that the securities are restricted securities and you understand the meaning of the term "restricted securities." You further represent that you were not solicited by publication of any advertisement in connection with the receipt of the shares and that you have consulted tax counsel as needed regarding the shares.

1.3 Company agrees to reimburse you for out-of-pocket expenses incurred by you in connection with your service (including out-of-pocket expenses, transportation, and airfare on company business, provided that such expenses are against original and valid receipts (the "Expenses").

1.4 Payment of the Expenses, as applicable, shall be made against your itemized invoice following the receipt of the relevant invoice, which invoice shall be submitted to the Company within seven (7) days of the end of each calendar month during the term of this letter of appointment.

1.5 For the avoidance of any doubt, the Fee and the Options (subject to their terms) and the aforementioned Expenses constitute the full and final consideration for your appointment, and you shall not be entitled to any additional consideration, of any form, for your appointment and service.

2. The term of your appointment as a non-employee, director of the Company shall be for one year or until the next Meeting of Stockholders and shall be renewable on a yearly basis by vote of the shareholders or appointment by the board.

3. You will undertake such travelling as may reasonably be necessary for the performance of your duties, including travelling for board meetings and site visits if required.

4. You will undertake such duties and powers relating to the Company and any subsidiaries or associated companies (the "Group") as the Board may from time to time reasonably request. The Board as a whole is collectively responsible for promoting the success of the Company by directing and supervising the Company's affairs, inter alia, as follows:

4.1 Providing entrepreneurial leadership of the Group within a framework of prudent and effective controls which enable risk to be assessed and managed; and

4.2 Setting the Group's strategic aims, ensures that the necessary financial and human resources are in place for the Group to meet its objectives and reviews of management performance; and

4.3 Setting the Group's values and standards and ensure that its obligations to its shareholders and others are understood and met.

4.3.1 Managing conflicts of interest that may arise in board meetings; and

4.3.2 Ensuring that all board members are acting in the best interests of all shareholders.

5. Confidential Information.

5.1 You undertake to the Company that you shall maintain in strict confidentiality all trade, business, technical or other information regarding the Company, the Group, its affiliated entities and their business affairs including, without limitation, all marketing, sales, technical and business know-how, intellectual property, trade secrets, identity and requirements of customers and prospective customers, the Company's methods of doing business and any and all other information relating to the operation of the Company (collectively, the "Confidential Information"). You shall at no time disclose any Confidential Information to any person, firm, or entity, for any purpose unless such disclosure is required in order to fulfil your responsibilities as director. You further undertake that you shall not use such Confidential Information for personal gain.

"Confidential Information" shall not include information that (i) is or becomes part of the public domain other than as a result of disclosure by You, (ii) becomes available to you on a non-confidential basis from a source other than the Company, provided that the source is not bound with respect to that information by a confidentiality agreement with the Group or is otherwise prohibited from transmitting that information by a contractual legal or other obligation, or (iii) can be proven by you to have been in your possession prior to disclosure of the information by the Company. In the event that you are requested or required (by oral questions, interrogatories, requests for information or documents, subpoena, civil investigative demand or other process) to disclose any Confidential Information, it is agreed that you, to the extent practicable under the circumstances, will provide the Company with prompt notice of any such request or requirement so that the Company may seek an appropriate protective order or waive compliance with this paragraph 5. If a protective order or the receipt of a waiver hereunder has not been obtained, you may disclose only that portion of the Confidential Information which you are legally compelled to disclose.

5.2 Blackout Period. You understand that we have, or intend to have, a policy pursuant to which no officer, director or key executive may not engage in transactions in our stock during the period commencing the end of a fiscal quarter and ending the day after the financial information for the quarter and year have been publicly released. If you become a member of the audit committee and you have information concerning our financial results at any time, you may not engage in transactions in our securities until the information is publicly disclosed.

6. Term and Termination

6.1 Subject to paragraph 6.2 hereunder, this appointment shall terminate immediately and without claim for compensation on the occurrence of any of the following events:

6.1.1 If you resign as a Director of the Company for any reason; and/or

6.1.2 If you are removed or not re-appointed as a Director of the Board of the Company at a General Meeting of shareholders of the Company in accordance with the requirements of the Business Corporation Law of the State of Nevada and/or any other applicable law or regulation (the "Law") and/or the Company's Articles of Incorporation; and/or

6.1.3 If you have been declared bankrupt or made an arrangement or composition with or for the benefit of your creditors; and/or

6.1.4 If you have been disqualified from acting as a Director (including, but not limited to, an event in which you are declared insane or become of unsound mind or become physically incapable of performing your functions as director for a period of at least sixty (60) days; and/or

6.1.5 If an order of a court having jurisdiction over the Company requires you to resign.

6.2 Any termination of this letter of appointment shall be without payment of damages or compensation (except that you shall be entitled to any accrued Fees or Expenses properly incurred under the terms of this letter of appointment prior to the date of such termination).

7. The Company will put directors' and officers' liability insurance in place within sixty (60) days of this Agreement if not already in place, and will use commercial reasonable efforts to maintain such insurance coverage for the full term of your appointment.

8. On termination of this appointment, you shall return all property belonging to the Group, together with all documents, papers, disks and information, howsoever stored, relating to the Group and used by you in connection with your position with the Company.

9. Subject to the proper performance of your obligations to the Company under this letter of appointment and any applicable law, the Company agrees that you will be free to accept other appointments, directorships and chairmanships provided that:

9.1 They do not in any way conflict with the interests of the Company or any member of the Group; and

9.2 They do not restrict you from devoting the necessary time and attention properly to services to be performed under this letter of appointment; and

9.3 In the event that you become aware of any potential conflicts of interest, these must be disclosed to the Chairman and/or the Chief Executive Officer (the "**CEO**") of the Company as soon as they become apparent.

10. The performance of individual Directors, the Chairman and the Board and its committees is evaluated annually. If, in the interim, there are any matters which cause you concern about your position, you should discuss them with the Chairman and/or the CEO as soon as is appropriate.

11. In addition to any right pursuant to applicable law, occasions may arise when you consider that you need professional advice in the furtherance of your duties as a director. Circumstances may occur when it will be appropriate for you to seek such advice from independent advisors at the Company's expense, to the extent provided under applicable law and subject to the prior written approval of the CEO and/or the Board.

12. This letter refers to your appointment as a Director of the Company and your membership on the committees of the Board.

13. You shall ensure that you comply at all times with the Company's inside trading policies as in effect from time to time.

14. You shall discharge your general duties as a Director pursuant to the Company's Articles of Incorporation and applicable law.

15. This letter of appointment shall be governed by and construed in accordance with the law of the State of Massachusetts.

Please sign the attached copy of this letter and return it to Xenetic to signify your acceptance of the terms set out above.

Sincerely yours,

XENETIC BIOSCIENCES INC.

/s/ Jeffrey Eisenberg
Name: Jeffrey Eisenberg Title: Chief Operating Officer

AGREED AND ACKNOWLEDGED BY:

/s/ Adam Logal
Name of Director: Adam Logal

Exhibit 10.49

Xenetic Bioscience, Inc.
99 Hayden Avenue, Suite 230
Lexington, MA 02421
p 781-778-7720
e info@xeneticbio.com

October 11, 2017

James E. Callaway, Ph.D
4893 Drakewood Terrace
San Diego, CA 92130

Dear James:

This Letter Agreement (the "Agreement") is to confirm the terms of your proposed appointment on August 14, 2017 (the "Effective Date") as a non-employee, independent Director of Xenetic Biosciences, Inc. (the "Company").

Overall, in terms of time commitment, we expect your attendance at all the Board meetings and meetings of such committees of the Board that you will be appointed to (as applicable). In addition, you will be expected to devote appropriate preparation time ahead of each meeting. By accepting this appointment, you have confirmed that you are able to allocate sufficient time to meet the expectations of this position.

1. Consideration. For and in consideration of the services to be performed by you, the Company agrees to compensate you as follows:

1.1 Director Fee. A director fee equal to $50,000 (Fifty Thousand U.S. Dollars) per annum, payable quarterly (the "Board Meeting Fee") will be the cash compensation for your role as a director, as well as any board committees, as chair or as a member, you may participate.

1.2 Stock Options. Subject to all approvals required by law, the Company will grant you, pursuant to an equity incentive plan or such other plan to be adopted by the Company (the "Plan") and upon such terms and conditions as determined by the Compensation Committee or the Board (as applicable), an option to purchase Twenty-Five Thousand (25,000) shares of common stock of the Company at a strike price determined by the closing price of the common stock on the date of this Agreement (the "Initial Grant"). This option shall be exercisable as provided herein and shall vest quarterly over twelve months so long as you are a member of our board of directors. An additional option to purchase 25,000 shares of Company common stock shall be granted for service each year at the date of the Company's Annual Meeting of Shareholders commencing with the 2018 Annual Meeting of Shareholders. The exercise price shall be determined by the closing price of the common stock on the date of such grant.

If your board service is terminated or ends for any reason, all granted Options that have not vested — shall be forfeited, and any Options that have vested but have not been exercised may be exercisable by you any time within three (3) months of the termination of your board position (the "Termination Exercise Period"). Any Options that are not exercised within the Termination Exercise Period, shall expire immediately.

1.2.1 Term of Options. All Options, if and to the extent vested according to Section 1.2 above, shall be in effect for a period of 10 years commencing immediately after the granting of all Options granted to you under this letter of appointment, and shall expire immediately thereafter, unless terminated sooner as provided in Section 1.2. Without derogating from the aforesaid, if the Plan that shall be approved by the Company shall include additional provisions related to expiration of Options, such provisions shall also apply with respect to all Options granted to you under this letter of appointment.

1.2.1a Vesting. All Options granted to you shall vest as provided in Section 1.2.

1.2.lb Price. The exercise price of the Options shall be equal to the Company's closing stock price on the date of your grant.

1.2.1c General. All options granted to you shall be in effect subject to your continuous service as a Director and subject to the terms and conditions of the Company's Stock Option Plan (the "Plan"), including such terms related to vesting and expiration, and subject to such terms and conditions as will be approved by the Company, at its sole discretion. In case of contradiction between the provisions of this letter of appointment and the provisions of the Plan, the provisions of the Plan shall supersede.

1.2.1d Certain Representations. You represent and agree that you are accepting the option to purchase shares of common stock being issued to you pursuant to this Agreement for your own account and not with a view to or for sale of distribution thereof. You understand that the securities are restricted securities and you understand the meaning of the term "restricted securities." You further represent that you were not solicited by publication of any advertisement in connection with the receipt of the shares and that you have consulted tax counsel as needed regarding the shares.

1.3 Company agrees to reimburse you for out-of-pocket expenses incurred by you in connection with your service (including out-of-pocket expenses, transportation, and airfare on company business, provided that such expenses are against original and valid receipts (the "Expenses").

1.4 Payment of the Expenses, as applicable, shall be made against your itemized invoice following the receipt of the relevant invoice, which invoice shall be submitted to the Company within seven (7) days of the end of each calendar month during the term of this letter of appointment.

1.5 For the avoidance of any doubt, the Fee and the Options (subject to their terms) and the aforementioned Expenses constitute the full and final consideration for your appointment, and you shall not be entitled to any additional consideration, of any form, for your appointment and service.

2. The term of your appointment as a non-employee, director of the Company shall be for one year or until the next Meeting of Stockholders and shall be renewable on a yearly basis by vote of the shareholders or appointment by the board.

3. You will undertake such travelling as may reasonably be necessary for the performance of your duties, including travelling for board meetings and site visits if required.

4. You will undertake such duties and powers relating to the Company and any subsidiaries or associated companies (the "Group") as the Board may from time to time reasonably request. The Board as a whole is collectively responsible for promoting the success of the Company by directing and supervising the Company's affairs, inter alia, as follows:

4.1 Providing entrepreneurial leadership of the Group within a framework of prudent and effective controls which enable risk to be assessed and managed; and

4.2 Setting the Group's strategic aims, ensures that the necessary financial and human resources are in place for the Group to meet its objectives and reviews of management performance; and

4.3 Setting the Group's values and standards and ensure that its obligations to its shareholders and others are understood and met.

4.3.1 Managing conflicts of interest that may arise in board meetings; and

4.3.2 Ensuring that all board members are acting in the best interests of all shareholders.

5. Confidential Information.

5.1 You undertake to the Company that you shall maintain in strict confidentiality all trade, business, technical or other information regarding the Company, the Group, its affiliated entities and their business affairs including, without limitation, all marketing, sales, technical and business know-how, intellectual property, trade secrets, identity and requirements of customers and prospective customers, the Company's methods of doing business and any and all other information relating to the operation of the Company (collectively, the "Confidential Information"). You shall at no time disclose any Confidential Information to any person, firm, or entity, for any purpose unless such disclosure is required in order to fulfil your responsibilities as director. You further undertake that you shall not use such Confidential Information for personal gain.

"Confidential Information" shall not include information that (i) is or becomes part of the public domain other than as a result of disclosure by You, (ii) becomes available to you on a non-confidential basis from a source other than the Company, provided that the source is not bound with respect to that information by a confidentiality agreement with the Group or is otherwise prohibited from transmitting that information by a contractual legal or other obligation, or (iii) can be proven by you to have been in your possession prior to disclosure of the information by the Company. In the event that you are requested or required (by oral questions, interrogatories, requests for information or documents, subpoena, civil investigative demand or other process) to disclose any Confidential Information, it is agreed that you, to the extent practicable under the circumstances, will provide the Company with prompt notice of any such request or requirement so that the Company may seek an appropriate protective order or waive compliance with this paragraph 5. If a protective order or the receipt of a waiver hereunder has not been obtained, you may disclose only that portion of the Confidential Information which you are legally compelled to disclose.

5 . 2 Blackout Period. You understand that we have, or intend to have, a policy pursuant to which no officer, director or key executive may not engage in transactions in our stock during the period commencing the end of a fiscal quarter and ending the day after the financial information for the quarter and year have been publicly released. If you become a member of the audit committee and you have information concerning our financial results at any time, you may not engage in transactions in our securities until the information is publicly disclosed.

6. **Term and Termination**

6.1 Subject to paragraph 6.2 hereunder, this appointment shall terminate immediately and without claim for compensation on the occurrence of any of the following events:

6.1.1 If you resign as a Director of the Company for any reason; and/or

6.1.2 If you are removed or not re-appointed as a Director of the Board of the Company at a General Meeting of shareholders of the Company in accordance with the requirements of the Business Corporation Law of the State of Nevada and/or any other applicable law or regulation (the "Law") and/or the Company's Articles of Incorporation; and/or

6.1.3 If you have been declared bankrupt or made an arrangement or composition with or for the benefit of your creditors; and/or

6.1.4 If you have been disqualified from acting as a Director (including, but not limited to, an event in which you are declared insane or become of unsound mind or become physically incapable of performing your functions as director for a period of at least sixty (60) days; and/or

6.1.5 If an order of a court having jurisdiction over the Company requires you to resign.

6.2 Any termination of this letter of appointment shall be without payment of damages or compensation (except that you shall be entitled to any accrued Fees or Expenses properly incurred under the terms of this letter of appointment prior to the date of such termination).

7. The Company will put directors' and officers' liability insurance in place within sixty (60) days of this Agreement if not already in place, and will use commercial reasonable efforts to maintain such insurance coverage for the full term of your appointment.

8. On termination of this appointment, you shall return all property belonging to the Group, together with all documents, papers, disks and information, howsoever stored, relating to the Group and used by you in connection with your position with the Company.

9. Subject to the proper performance of your obligations to the Company under this letter of appointment and any applicable law, the Company agrees that you will be free to accept other appointments, directorships and chairmanships provided that:

9.1 They do not in any way conflict with the interests of the Company or any member of the Group; and

9.2 They do not restrict you from devoting the necessary time and attention properly to services to be performed under this letter of appointment; and

9.3 In the event that you become aware of any potential conflicts of interest, these must be disclosed to the Chairman and/or the Chief Executive Officer (the "CEO") of the Company as soon as they become apparent.

10. The performance of individual Directors, the Chairman and the Board and its committees is evaluated annually. If, in the interim, there are any matters which cause you concern about your position, you should discuss them with the Chairman and/or the CEO as soon as is appropriate.

11. In addition to any right pursuant to applicable law, occasions may arise when you consider that you need professional advice in the furtherance of your duties as a director. Circumstances may occur when it will be appropriate for you to seek such advice from independent advisors at the Company's expense, to the extent provided under applicable law and subject to the prior written approval of the CEO and/or the Board.

12. This letter refers to your appointment as a Director of the Company and your membership on the committees of the Board.

13. You shall ensure that you comply at all times with the Company's inside trading policies as in effect from time to time.

14. You shall discharge your general duties as a Director pursuant to the Company's Articles of Incorporation and applicable law.

15. This letter of appointment shall be governed by and construed in accordance with the law of the State of Massachusetts.

Please sign the attached copy of this letter and return it to Xenetic to signify your acceptance of the terms set out above.

Sincerely yours,

XENETIC BIOSCIENCES INC.

/s/ Jeffrey Eisenberg
Name: Jeffrey Eisenberg

Title: Chief Operating Officer

AGREED AND ACKNOWLEDGED BY:

/s/ James E. Callaway, Ph.D
Name of Director: James E. Callaway, Ph.D

Exhibit 21.1

SUBSIDIARIES OF REGISTRANT

Subsidiary	**Country / State of Incorporation**
Xenetic Biosciences (UK), Ltd.	United Kingdom registered company
Lipoxen Technologies, Ltd.	United Kingdom registered company
Xenetic Technologies, Inc.	Delaware
SymbioTec, GmbH	German Registered Company

Exhibit 23.1

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM'S CONSENT

We consent to the incorporation by reference in the Registration Statement of Xenetic Biosciences, Inc. on Form S-8 [File Nos. 333-222272 and 333-218024] of our report dated March 30, 2018, which includes an explanatory paragraph as to the Company's ability to continue as a going concern, with respect to our audits of the consolidated financial statements of Xenetic Biosciences, Inc. as of December 31, 2017 and 2016 and for each of the two years in the period ended December 31, 2017, which report is included in this Annual Report on Form 10-K of Xenetic Biosciences, Inc. for the year ended December 31, 2017.

/s/ Marcum LLP

Marcum LLP
Boston, Massachusetts
March 30, 2018

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO EXCHANGE ACT RULES 13a-14(a) AND 15d-14(a),
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Jeffrey F Eisenberg, certify that:

1. I have reviewed this annual report on Form 10-K of Xenetic Biosciences, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: March 30, 2018

By: /s/ Jeffrey F Eisenberg
Jeffrey F. Eisenberg
Principal Executive Officer

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO EXCHANGE ACT RULES 13a-14(a) AND 15d-14(a),
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, James Parslow, certify that:

1. I have reviewed this annual report on Form 10-K of Xenetic Biosciences, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: March 30, 2018

By: /s/ James Parslow
James Parslow
Principal Financial Officer

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Xenetic Biosciences, Inc. (the "Company") for the fiscal year ended December 31, 2017, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), we, the undersigned officers of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 30, 2018

/s/ Jeffrey F. Eisenberg
Jeffrey F. Eisenberg
Chief Executive Officer
(Principal Executive Officer)

/s/James Parslow
James Parslow
Chief Financial Officer
(Principal Financial Officer)