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, 2019

☐ **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.)**

40 Speen Street, Suite 102
Framingham, MA 01701
(Address of principal executive offices and zip code)

781-778-7720
(Registrant's telephone number, including area code)

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value per share	XBIO	The NASDAQ Capital Market
Purchase Warrants	XBIOW	The NASDAQ Capital Market

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

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days: Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files): Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer" "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

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

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

The aggregate market value of the voting and non-voting common stock held by non-affiliates of the registrant as of June 28, 2019, the last business day of the registrant's most recently completely second fiscal quarter, based upon the closing price of the registrant's common stock on the NASDAQ Capital Market on that date of $11.25, was approximately $5,342,529. 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 6, 2020, the number of outstanding shares of the registrant's Common Stock was 6,284,915.

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, information statement or an amendment to this Annual Report on Form 10-K for its 2020 Annual Meeting of Stockholders. The registrant intends to file a definitive proxy statement, information statement or an amendment to this Annual Report on Form 10-K with the Securities and Exchange Commission no later than 120 days after the end of the registrant's fiscal year ended December 31, 2019.

XENETIC BIOSCIENCES, INC.
2019 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 develop our proposed drug candidates; our expectations regarding the nature, timing and extent of clinical trials and proposed clinical trials including the timing of generating clinical data from these 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; the development of the XCART™ CAR T ("Chimeric Antigen Receptor T Cell") technology; our plans to apply the XCART technology to advance cell-based therapeutics by targeting the unique B cell receptor on the surface of an individual patient's malignant tumor cells for the treatment of B-cell lymphomas; our beliefs regarding the expected results of the XCART technology, including its potential to significantly enhance the safety and efficacy of cell therapy for B-cell lymphomas by generating patient and tumor specific CAR T cells; and our anticipating that our primary focus will now be on advancing the XCART technology regulatory approval and commercialization technology.

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.

Some factors that could cause actual results to differ materially include without limitation:

- our need to raise additional working capital in the future for the purpose of further developing our XCART technology and to continue as a going concern;
- our ability to finance our business;
- our ability to successfully execute, manage and integrate key acquisitions and mergers, including integration of the acquisition of the XCART technology;
- product development and commercialization risks, including our ability to successfully develop the XCART technology;
- the impact of adverse safety outcomes and clinical trial results for CAR-T cell therapies;
- our ability to secure and maintain a manufacturer for the XCART technology;
- our ability to successfully commercialize our current and future drug candidates;
- our ability to achieve milestone and other payments associated with our current and future 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;
- 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;
- general economic and business conditions, as well as inflationary trends; and
- other factors set forth in the Risk Factors section of our Annual Report on Form 10-K and in subsequent filings with the Securities and Exchange Commission ("SEC").

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, including, but not limited to, those discussed in the section titled "Risk Factors." 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. We intend that all forward-looking statements be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995.

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 XCART™, OncoHist™, PolyXen®, ErepoXen™ and ImuXen™ 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 biopharmaceutical company focused on advancing XCART, a personalized CAR T cell platform technology engineered to target patient-specific tumor neoantigens. The Company is initially advancing cell-based therapeutics targeting the unique B-cell receptor on the surface of an individual patient's malignant tumor cells, for the treatment of B-cell lymphomas. The XCART technology, developed by the Scripps Research Institute (the "Institute") in collaboration with the Shemyakin-Ovchinnikov Institute of Bioorganic Chemistry ("IBCH"), is believed to have the potential to significantly enhance the safety and efficacy of cell therapy for B-cell lymphomas by generating patient- and tumor-specific CAR T cells. On March 1, 2019, we entered into agreements to acquire the XCART technology (the "Transaction") and closed the Transaction on July 19, 2019 (the "Closing Date") concurrent with the completion of an approximate $15 million public offering (the "Offering").

More than 70,000 new cases of non-Hodgkin Lymphoma ("NHL") are diagnosed each year in the United States, and more than 19,000 patients die of this group of diseases annually. Most forms of NHL, including follicular lymphoma, mantle cell lymphoma, marginal zone lymphoma, lymphoplasmacytic lymphoma, and small lymphocytic lymphoma, which account collectively for ~45% of all cases of NHL, are incurable with available therapies, except for allo-SCT. However, many NHL patients are not suitable candidates for allo-SCT, and this treatment is also limited by significant rates of morbidity and mortality due to graft versus host disease. Aggressive B-cell lymphomas such as diffuse large B-cell lymphoma account for 30-35% of NHL. The majority of patients with aggressive B-NHL are successfully treated with combination chemotherapy, but a significant portion relapse or have refractory disease, and the outcome of these patients is poor.

CAR-T cell therapies are an innovative approach in which a patient's T cells are genetically modified to carry chimeric antigen receptors ("CARs"). High objective response rates have been reported in some hematological malignancies, but patients treated with CAR-T cell therapies can have serious and sometimes fatal toxicities, which include instances in which the CAR-T cells have caused high levels of cytokines due to over-activation, referred to as "cytokine release syndrome," or CRS, neurologic toxicities and cases in which CAR-T cells have attacked healthy organs. In each case, these toxicities have sometimes resulted in death. HSCT, also known as bone marrow transplantation, has for decades been curative for many patients with hematological cancers or orphan inherited blood disorders. However, adoption of HSCT to date has been limited by the risks of transplant-related morbidity and mortality from graft-versus-host-disease, or GvHD, and the potential for serious infections or cancer recurrence due to the lack of an effective immune system following a transplant.

The XCART technology platform was designed by its originators to utilize an established screening technique to identify peptide ligands that bind specifically to the unique B-cell receptor ("BCR") on the surface of an individual patient's malignant tumor cells. The peptide is then inserted into the antigen-binding domain of a CAR T cell, and a subsequent transduction/transfection process is used to engineer the patient's T cells into a CAR T format which redirects the patient's T cells to attack the tumor. Essentially, the XCART screening platform is the inverse of a typical CAR T screening protocol wherein libraries of highly specific antibody domains are screened against a given target. In the case of XCART screening, the target is itself an antibody domain, and hence highly specific by its nature. The XCART technology creates the possibility of personalized treatment of lymphomas utilizing a CAR with an antigen-binding domain that should only recognize, and only be recognized by, the unique BCR of a particular patient's B-cell lymphoma. An expected result for XCART is limited off-tumor toxicities, such as B-cell aplasia. Our clinical development program will seek to confirm the early preclinical results, and to demonstrate a more attractive safety profile than existing therapies. We anticipate that our primary focus will now be on advancing this technology through regulatory approval and commercialization.

Additionally, our proprietary drug development platform, PolyXen, enables next-generation biological drugs by modifying their half-life and other pharmacological properties. PolyXen has been demonstrated in human clinical trials to confer prolonged half-life on biotherapeutics such as recombinant human erythropoietin 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 continue to commit a significant amount of our 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. We are receiving ongoing royalties pursuant to a license of our PolyXen technology to an industry partner.

We also have oncology therapeutic investigational drug candidate 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. 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 endometrial cancer in conjunction with progesterone therapy. We commenced a Phase 2 trial under an IND in 2017, with the first patient dosed in October 2017. We closed patient enrollment in the trial in March 2019 as a result of slower than expected progress on the trial resulting from patient enrollment and retention challenges and have suspended further development of XBIO-101. We currently have no plans to continue development of XBIO-101.

Although we hold a broad patent portfolio, the focus of our internal development efforts in 2019 was limited to winding down the XBIO-101 Phase 2 trial and preliminary development efforts associated with the XCART technology.

We were incorporated under the laws of the State of Nevada in August 2011. We, directly or indirectly, through our wholly-owned subsidiary, Xenetic Biosciences (U.K.) Limited ("Xenetic U.K."), and its wholly-owned subsidiaries, Lipoxen Technologies Limited ("Lipoxen"), Xenetic Bioscience, Incorporated ("XTI") and SymbioTec, GmbH ("SymbioTec"), own various U.S. federal trademark registrations and applications, and unregistered trademarks and service marks, including but not limited to XCART, OncoHist, PolyXen, ErepoXen and ImuXen.

Our Strategy

In July 2019 we acquired the XCART platform, a novel CAR T technology engineered to target patient- and tumor-specific neoantigens (see "Business Developments" for a description of the Transaction and "Our Technology and Drug Candidates" for a description of the technology). We believe these personalized T cell therapies have the potential to offer cancer patients substantial benefits over the existing standard of care and currently approved CAR T therapies. We plan to initially apply the XCART technology to develop cell-based therapeutics for the treatment of B-cell Lymphomas with our primary focus to advance this technology through regulatory approval and commercialization. We also intend to pursue industry collaborations and potential licenses to develop XCART for other uses and indications.

We plan to opportunistically 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 to us in the form of access to partner-generated clinical data, which is informative when contemplating potential monetization of our proprietary technology in larger markets. One aim of these efforts would be to drive incremental shareholder value and generate working capital to assist in providing the funding required to support our XCART development efforts.

We intend to pursue orphan drug designations and accelerated approval pathways 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 certain market exclusivities.

We intend to advance development of our drug candidates primarily through the use of contract manufacturing and contract research organizations ("CROs") 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.

Business Developments

XCART Technology

On March 1, 2019 (the "Signing Date") we entered into agreements with Hesperix SA, a Swiss Corporation ("Hesperix") and Opko Pharmaceuticals, LLC ("OPKO") to acquire the XCART technology. We entered into a Share Purchase Agreement, as amended (the "Share Purchase Agreement"), with Hesperix, the owners of Hesperix (each, a "Seller" and collectively, the "Sellers"), and Alexey Andreevich Vinogradov, as the representative of each Seller, pursuant to which we purchased from Sellers all of the issued and outstanding shares of capital stock of Hesperix.

Under the terms of the Share Purchase Agreement, we issued to Sellers an aggregate of Four Hundred Six Thousand Two Hundred Forty-Six (406,246) shares of our Common Stock (the "Transaction Shares") at the time of the closing. In addition, the Share Purchase Agreement contains customary representations and warranties relating to each Seller and about the condition of the Company and Hesperix. We issued the Transaction Shares pursuant to a registration statement on Form S-4.

On the Signing Date and in connection with the Transaction, Hesperix entered into an assignment agreement (the "Hesperix Assignment Agreement") with IBCH, Pharmsynthez, a Russian pharmaceutical company, and certain other parties thereto (collectively, the "Assignors"), pursuant to which the Assignors have agreed, among other things, to sell, assign, transfer, and convey unto Hesperix all of their individual right, title, and interest throughout the world in and to patents related to "Articles And Methods Directed To Personalized Therapy Of Cancer," and the related know-how. Hesperix has agreed to pay each of IBCH and Pharmsynthez a royalty rate in the low single digit range based on the net sales of products in each country in which, in the absence of the Hesperix Assignment Agreement, the manufacture, use, offer for sale, sale, or importation of such product would infringe a valid claim of a patent.

Also on the Signing Date, we entered into an assignment agreement with OPKO (the "OPKO Assignment Agreement"), pursuant to which the Company will acquire and accept, all of OPKO's right, title and interest in and to that certain Intellectual Property License Agreement (the "IP License Agreement"), entered into between the Institute and OPKO regarding certain patents related to "Articles And Methods Directed To Personalized Therapy Of Cancer" and in which the Institute agreed to grant an exclusive royalty-bearing license, to the patent rights owned by the Institute to OPKO, and OPKO has agreed to pay the Institute a royalty rate in the low single digit range based on the net sales of products in each country in which, in the absence of the IP License Agreement, the manufacture, use, offer for sale, sale, or importation of such product would infringe a valid claim of a patent or pending application.

Under the terms of the OPKO Assignment Agreement and the IP License Agreement, we issued One Hundred Sixty Four Thousand Sixty Two (164,062) shares of our Common Stock to OPKO and Fifty-Four Thousand Six Hundred Eighty Seven (54,687) shares of our Common Stock to the Institute at the time of the closing. In addition, the OPKO Assignment Agreement contains customary representations and warranties relating to OPKO and the IP License Agreement. The Transaction closed on July 19, 2019.

The Offering

On July 17, 2019, we entered into an underwriting agreement (the "Underwriting Agreement") with Maxim Group LLC (the "Underwriter"), relating to our Offering of 1,730,000 shares (the "Shares") of the Company's common stock, par value $0.001 (the "Common Stock"), Prefunded Warrants to purchase 570,000 shares of Common Stock (the "Prefunded Warrants"), and warrants to purchase 2,300,000 shares of the Common Stock (the "Purchase Warrants," and together with the Shares and the Prefunded Warrants, the "Firm Securities"). Each Share was sold together with one Purchase Warrant at a combined public offering price of $6.50 per Share and Purchase Warrant. Each Pre-funded Warrant purchased was sold together with one Purchase Warrant at a combined public offering price of $6.49 per Prefunded Warrant and Purchase Warrant. The Prefunded Warrants were exercisable beginning on July 17, 2019 at an exercise price of $0.01 per share. The holders of the Prefunded Warrants did not have the right to exercise any portion of the Prefunded Warrant if the holder (together with its affiliates) would beneficially own in excess of 4.99% of the number of shares of our Common Stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Prefunded Warrants. Pursuant to the Underwriting Agreement, we also granted the Underwriter a 45-day option to purchase up to an additional 345,000 shares of Common Stock and/or Purchase Warrants to purchase up to 345,000 shares of Common Stock (the "Additional Securities," and together with the Firm Securities, the "Securities"), at the public offering price less discounts and commissions.

The Securities were offered, issued, and sold pursuant to an effective Registration Statement on Form S-1 (Reg. No. 333-231508) and accompanying prospectus filed with the SEC under the Securities Act of 1933, as amended.

On the Closing Date, we completed the Offering resulting in gross proceeds to us of approximately $15.0 million before deducting the underwriting discount and offering fees and expenses payable by us. In addition, on the Closing Date, the Underwriter exercised its overallotment option with respect to 160,000 Purchase Warrants, resulting in additional gross proceeds of $1,600. We intend to use the net proceeds from the Offering of approximately $13.4 million to fund our research, development and clinical programs, including the development of the XCART technology acquired in the Transaction, and for other general corporate purposes. All of the Prefunded Warrants were exercised during the year ended December 31, 2019, resulting in $5,700 of net proceeds to us.

The Purchase Warrants were immediately exercisable at a price of $13.00 per share of Common Stock and expire five years from the date of issuance. The Purchase Warrants began trading on NASDAQ on July 23, 2019 under the symbol "XBIOW." The Purchase Warrants also provide that if the weighted-average price of Common Stock on any trading day on or after 30 days after issuance is lower than the then-applicable exercise price per share, each Purchase Warrant may be exercised, at the option of the holder, on a cashless basis for one share of Common Stock. The weighted-average price of our Common Stock 30 days after issuance was lower than the applicable exercise price per share. As a result, Purchase Warrants to purchase 2.2 million shares were exercised on a cashless basis into 2.2 million shares of our Common Stock during the year ended December 31, 2019.

Reverse Stock Split

On June 25, 2019, we effected a reduction, on a 1 for 12 basis, in our authorized Common Stock, par value $0.001, along with a corresponding and proportional decrease in the number of shares issued and outstanding (the "Reverse Stock Split"). On the effective date of the Reverse Stock Split, (i) every 12 shares of Common Stock were reduced to one share of Common Stock, with any fractional amounts rounded up to one share; (ii) the number of shares of Common Stock into which each outstanding warrant, restricted stock unit, or option to purchase Common Stock were proportionately reduced on the same basis as the Common Stock; (iii) the exercise price of each outstanding warrant or option to purchase Common Stock were proportionately increased on a 1 for 12 basis; and (iv) the number of shares of Common Stock into which each share of preferred stock could be converted were proportionately reduced on the same basis as the Common Stock. Unless otherwise indicated, all of the share numbers, share prices, and exercise prices have been adjusted, on a retroactive basis, to reflect this Reverse Stock Split.

On June 21, 2019, we filed a Certificate of Change to the Company's Articles of Incorporation with the Secretary of State of Nevada to effect the Reverse Stock Split. The Reverse Stock Split was effective at 12:01 a.m., eastern Time, on June 25, 2019. No fractional shares were issued as a result of the Reverse Stock Split and any remaining share fractions were rounded up to the nearest whole share, resulting in 1,442 new shares of Common Stock being issued to existing holders of our Common Stock.

Increase in Authorized Shares

On June 19, 2019, shareholders of the Company voted to approve an amendment to our Articles of Incorporation to increase the authorized shares of Common Stock to 150,000,000 shares on a pre-Reverse Stock Split basis (the "Authorized Share Increase"). On June 24, 2019, we filed a Certificate of Amendment to the Company's Articles of Incorporation with the Secretary of the State of Nevada to effect the Authorized Share Increase as of June 25, 2019. As a result of the Authorized Share Increase and after giving effect to the Reverse Stock Split, we had 12,500,000 authorized shares of Common Stock.

Closing of Patient Enrollment in XBIO-101 Phase II EC Trial

We commenced a Phase II trial under an IND for XBIO-101 in 2017, with the first patient dosed in October 2017. We closed patient enrollment in the trial in March 2019 as a result of slower than expected progress on the trial resulting from patient enrollment and retention challenges and have suspended further development of XBIO-101.

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 internally 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 five core proprietary technologies including three platforms, small molecules and biologics covering multiple drug candidates and indications including XCART, XBIO-101, PolyXen, OncoHist and ImuXen. During the year ended December 31, 2019, our primary focus was on the management of the XBIO-101 Phase II clinical study and the preliminary development efforts associated with the XCART technology. We have not been actively pursuing development efforts for PolyXen, OncoHist and ImuXen due to capital constraints. As a result, we anticipate that the focus of our future internal development efforts will be limited to research and development of our XCART technology.

XCART	The XCART technology platform was designed by its originators to utilize an established screening technique to identify peptide ligands that bind specifically to the unique BCR on the surface of an individual patient's malignant tumor cells. The peptide is then inserted into the antigen-binding domain of a CAR T cell, and a subsequent transduction/transfection process is used to engineer the patient's T cells into a CAR T format which redirects the patient's T cells to attack the tumor. Essentially, the XCART screening platform is the inverse of a typical CAR T screening protocol wherein libraries of highly specific antibody domains are screened against a given target. In the case of XCART screening, the target is itself an antibody domain, and hence highly specific by its nature. The XCART technology creates the possibility of personalized treatment of lymphomas utilizing a CAR with an antigen-binding domain that should only recognize, and only be recognized by, the unique BCR of a particular patient's B-cell lymphoma. An expected result for XCART is limited off-tumor toxicities, such as B-cell aplasia. Our clinical development program will seek to confirm the early preclinical results, and to demonstrate a more attractive safety profile than existing therapies to support our preliminary discussions with the FDA in advance of an IND filing.
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 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 in 2019 was limited to research and development of XBIO-101 and XCART due to capital constraints.

Research, Outside Services and Collaborations

Through partner efforts, we are developing our pipeline of next-generation bio-therapeutics and novel oncology drugs based on our XCART and PolyXen proprietary technologies. In order to do this while efficiently managing our overhead, we rely on the services of contract manufacturers and CROs and our strategic collaborations. We currently do not have in-house research facilities to pursue these initiatives. Accordingly, continuous pipeline growth and advancement of our technologies and drug candidates is dependent on several important collaborations and strategic arrangements including our arrangements with:

- Pharmsynthez, a beneficial owner of over 5% of our Common Stock;
- Serum Institute of India Limited ("Serum Institute"), one of the world's largest vaccine manufacturers and one of India's largest biotech companies; and
- Takeda Pharmaceuticals Co. Ltd (formerly Shire plc) ("Takeda"), a global biopharmaceutical leader.

Accordingly, in addition to pursuing our development of the XCART technology, 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. However, other than royalty payments under a sublicense with Takeda, we do not anticipate any milestone or royalty payments in the near term, if at all. For further detail, please read the section titled "Significant Co-Development Collaborations and Strategic Arrangements" below.

Our Drug Candidate Pipeline

Our product pipeline contains a number of drug candidates under development internally and 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:

XCART

XCART is a personalized CAR T cell platform technology engineered to target patient-specific tumor neoantigens. We believe XCART has the potential to offer cancer patients substantial benefits over the existing standard of care and currently approved CAR T therapies including enhanced the safety and efficacy of cell therapy for B-cell lymphomas. We are initially advancing cell-based therapeutics targeting the unique B-cell receptor on the surface of an individual patient's malignant tumor cells, for the treatment of B-cell lymphomas.

On March 1, 2019 we entered into agreements with Hesperix and OPKO to acquire all of the right, title, and interest throughout the world in and to patents related to the XCART technology and closed the Transaction on July 19, 2019. By acquiring this novel and differentiated CAR T technology, the Company will be positioned in a field that is at the forefront in the development of new oncology therapeutics. The XCART platform was designed to target personalized, patient-specific tumor neoantigens and has demonstrated proof of mechanism in B-cell lymphoma, an area of significant unmet medical need. In addition, the acquisition of XCART fits with our current strategy of focusing on research addressing unmet needs in oncology. Our R&D efforts will focus initially on leveraging the XCART platform to develop cell-based therapeutics for the treatment of B-cell Non-Hodgkin lymphomas, an initial global market opportunity estimated to exceed $5 billion per year.

ErepoXen

ErepoXen, or polysialylated erythropoietin ("PSA-EPO"), 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 are not pursuing clinical development of ErepoXen but continue to entertain out-license opportunities for 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.

In addition, Serum Institute finished Phase I/II clinical trials in India of ErepoXen for in-center-dialysis patients and plans to submit a clinical trial application to conduct a Phase III clinical trial for PSA-EPO in India in 2020.

SynBio received regulatory approval and commenced a Phase II(b)/III human clinical trial of ErepoXen in Russia and expects to have patient recruitment completed in 2020. SynBio intends to commence the commercialization and marketing stages of ErepoXen in the Russian and CIS markets subject to approval in such markets.

Drug Candidates in the Pipeline that are not Currently Active Internally or with Third Party Collaborators

XBIO-101

XBIO-101 is an internal candidate with orphan drug designation from the FDA for the potential treatment of progesterone receptor negative endometrial cancer in conjunction with progesterone therapy. An IND application was submitted for XBIO-101 and is in effect for our Phase II clinical trial in the U.S.

We acquired 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 Commonwealth of Independent States ("CIS"), from AS Kevelt ("Kevelt"), a wholly-owned subsidiary of Pharmsynthez. 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, our initial focus was on 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 over 20 years with millions of doses estimated to 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 a Phase II trial under an IND in 2017, with first patient dosed in October 2017. We closed patient enrollment in the trial in March 2019 as a result of slower than expected progress on the trial resulting from patient enrollment and retention challenges and have suspended further development of XBIO-101.

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 completed non-clinical toxicity studies and had a productive, in-person pre-IND meeting with the FDA in August 2015 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. However, our efforts in developing this drug candidate have been on hold since 2016 due to capital constraints.

Pipeline Expansion Opportunities

Operating under licenses from us within their home markets, our collaborators can potentially generate preclinical 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 the clinical toxicity data and other clinical data generated in the development of XBIO-101 and PolyXen, and potentially for OncoHist, and ImuXen, if any, for a variety of orphan oncology indications and next generation biologic drugs.

Significant Co-Development Collaborations and Strategic Arrangements

Takeda (f/k/a 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 Takeda, related to the development of a novel series of polysialylated blood coagulation factors. This collaboration with Takeda relies on our PolyXen technology to conjugate PSA to therapeutic blood-clotting factors, with the goal of improving the pharmacokinetic profile and extending the active half-life of these biologic molecules. The agreement grants Takeda a worldwide, exclusive, royalty-bearing license to our PSA patented and proprietary technology in combination with Takeda'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 May 2017, we announced that Takeda had terminated further development of SHP656, its polysialylated rFVIII drug candidate for the treatment of hemophilia, being developed using our proprietary PolyXen technology. While Takeda's Phase I/II 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. Based on Takeda's published research, there were no treatment-emergent adverse events reported. Though the trial's pre-defined once-weekly dosing criterion was not met, we continue to explore the potential for future collaborations with Takeda and Takeda has commenced a new, undisclosed internal project under the agreement.

In October 2017, we entered into a Right of Sublicense Agreement (the "Sublicense Agreement") with Baxalta Incorporated, Baxalta US Inc., and Baxalta GmbH (collectively, with their affiliates, "Baxalta") wholly-owned subsidiaries of Takeda. 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 products related to the treatment of blood and bleeding disorders ("Covered Products"). Pursuant to the Sublicense Agreement, Baxalta (i) paid us a one-time payment of seven million five hundred thousand dollars ($7,500,000) in November 2017 and (ii) agreed to pay us single digit royalty payments based upon net sales of the Covered Products throughout the term. We recognized the one-time payment of $7.5 million as license revenue in connection with this Sublicense Agreement during the year ended December 31, 2017. Royalty payments on net sales of the Covered Products commenced during the fourth quarter of 2019.

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 preclinical 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, 2019 and 2018, we 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 as if product does not meet the relevant success criteria for the product.

In furtherance of our co-development clinical objectives, on December 31, 2014, we granted SynBio a warrant to purchase 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 shares of our Common Stock to SynBio and Pharmsynthez non-director designees under the same terms and conditions of the SynBio 2014 Warrant. The vesting criteria for the SynBio 2014 warrants was not met and, as a result, the warrants expired during the year ended December 31, 2018. No warrants were exercised during the term of the warrants.

SynBio is a wholly-owned subsidiary of Pharmsynthez and all ownership percentages held by SynBio are combined with Pharmsynthez.

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 preclinical 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 Arrangement 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 a significant stockholder. Pharmsynthez directly, and indirectly through SynBio, has a share ownership in the Company of approximately 7.4% of the total issued and outstanding Common Stock as of December 31, 2019. In addition to its Common Stock ownership, Pharmsynthez holds outstanding warrants to purchase our Common Stock, approximately 1.5 million shares of our outstanding Series B Preferred Stock (as defined in Note 10, *Stockholders' Equity*), and all of our issued and outstanding Series A Preferred Stock (as defined in Note 10, *Stockholders' Equity*) through SynBio.

During the third quarter of 2019, we entered into a sponsored research agreement with Pharmsynthez related to experiments identified by us to support our efforts as we prepare for the initial tech transfer of the XCART methods to a future academic collaborator. Under the agreement, we made a $350,000 payment to Pharmsynthez during the third quarter of 2019, which is refundable on a pro rata basis if the project is terminated prematurely as a result of Pharmsynthez failing to perform the work.

During the fourth quarter of 2019, we entered into a loan agreement with Pharmsynthez (the "Pharmsynthez Loan"), pursuant to which we advanced Pharmsynthez an aggregate principal amount of up to $500,000 to be used for the development of Product A under the Co-Development Agreement. The Pharmsynthez Loan has a term of 15 months and shall accrue interest at a rate of 10% per annum. The Pharmsynthez Loan is guaranteed by all of the operating subsidiaries of Pharmsynthez, including SynBio and AS Kevelt, and is secured by all of the equity interests of the Company owned by Pharmsynthez and SynBio.

Serum Institute

In August 2011, we entered into a collaborative research and development agreement with Serum Institute (the "Serum Agreement") providing Serum Institute an exclusive license to use our PolyXen technology to research and develop one potential commercial product, PSA-EPO. Serum Institute is responsible for conducting all preclinical and clinical trials required to achieve regulatory approvals within certain predetermined 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. There are no milestone or other research-related payments due under the collaborative arrangement. No royalty, revenue or expense was recognized by us related to the Serum Institute arrangement during the years ended December 31, 2019 and 2018.

Through December 31, 2019, 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 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 our Common Stock to Serum Institute non-director designees under the same terms and conditions of the Serum 2014 Warrant. The Serum 2014 Warrant expired on December 30, 2019 and no warrants were exercised during the term of the Serum Warrants. 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 a related party of ours and had a share ownership of less than 1% of our total issued Common Stock as of December 31, 2019.

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 U.S. and in jurisdictions outside of the U.S. 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 U.S. Patent and Trademark Office ("USPTO") and in certain other developed countries. Our first issued patents begin to expire starting in 2021 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, 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 March 6, 2020, we directly or indirectly own, through our wholly-owned subsidiary, Xenetic U.K., and its wholly-owned subsidiaries, Lipoxen, XTI and SymbioTec, more than 170 U.S. and international patents that cover various aspects of our technologies. We have acquired or filed patent applications, and plan to file additional patent applications, covering various aspects of our XCART platform technology including all rights throughout the world in and to patents and patent applications related to "Articles And Methods Directed To Personalized Therapy Of Cancer," and our PolyXen platform technology covering polysialylation and advanced polymer conjugate technologies, respectively, as well as our other product candidates, including XBIO-101. 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 may also file additional patent applications, where possible, for XBIO-101 and OncoHist for additional uses and 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 H1.3. In addition, our licensed patent portfolio includes patents issued in jurisdictions outside of the U.S. and licensed patent applications pending in jurisdictions outside of the U.S. 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 treat 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-EPO, PSA-insulin and PSA-insulin like protein, SHP656 (PSA-rFVIII), PSA-DNase I and PSA-granulocyte colony stimulating factor (PSA-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 U.S. can provide exclusionary rights for 20 years from the earliest effective filing date. In addition, in certain instances, the term of an issued U.S. 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 U.S. 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 of 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 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 materials 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 would produce clinical materials for use in the development of drug candidates involving our PolyXen technology, including candidates developed by our partners. We do not have any agreements in place to manufacture clinical materials for use in the development of our XCART technology and anticipate seeking a third party manufacturer, including potentially an academic collaborator, for our clinical supply needs.

Government Regulation

General

Government authorities in the U.S., 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 biologics license application ("BLA") process before it may be legally marketed in the U.S.

U.S. Regulation

Drug Development Process

In the U.S., 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 U.S. 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.

U.S. 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 U.S. where there is no reasonable expectation that the cost of developing the drug or biologic will be recovered from sales in the U.S. 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

The Biologics Price Competition and Innovation Act, or BPCIA, amended the Public Health Service Act to authorize the FDA to approve similar versions of innovative biologics, commonly known as biosimilars. A competitor seeking approval of a biosimilar must file an application to establish its molecule as highly similar to an approved innovator biologic, among other requirements. The BPCIA, however, bars the FDA from approving biosimilar applications for 12 years after an innovator biological product receives initial marketing approval. This 12-year period of data exclusivity may be extended by six months, for a total of 12.5 years, if the FDA requests that the innovator company conduct pediatric clinical investigations of the product.

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 U.S. 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 preclinical 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 U.S. 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 U.S., 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 U.S. 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 U.S. 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 U.S. 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 U.S., 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 U.S., 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.

Reimbursement

In both domestic and foreign markets, sales and reimbursement of any approved products will depend, in part, on the extent to which the costs of such products will be covered by third-party payors, such as government health programs, commercial insurance and managed healthcare organizations. These third-party payors are increasingly challenging the prices charged for medical products and services and imposing controls to manage costs. The containment of healthcare costs has become a priority of federal and state governments and the prices of drugs have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. For example, in the U.S. there have been several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare, and reform government program reimbursement methodologies for drugs. Additionally, in May 2018, the U.S. presidential administration laid out a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. The Department of Health and Human Services, or HHS, has started the process of soliciting feedback on some of these measures and, at the same time, is immediately implementing others under its existing authority.

In January 2019, the HHS Office of Inspector General proposed modifications to U.S. federal healthcare Anti-Kickback Statute safe harbors which, among other things, will affect rebates paid by manufacturers to Medicare Part D plans, the purpose of which is to further reduce the cost of drug products to consumers. Although some of these and other proposals may require authorization through additional legislation to become effective, members of Congress and the presidential administration have indicated that they will continue to seek new legislative or administrative measures to control drug costs.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, to encourage importation from other countries and bulk purchasing.

Within the U.S., if we obtain appropriate approval in the future to market any of our product candidates, we may seek approval and coverage for those products under Medicaid, Medicare and the Public Health Service, or PHS, pharmaceutical pricing program and also seek to sell the products to federal agencies. Medicaid is a joint federal and state program that is administered by the states for low income and disabled beneficiaries. Under the Medicaid Drug Rebate Program, manufacturers are required to pay a rebate for each unit of product reimbursed by the state Medicaid programs. The amount of the rebate for each product is set by law and may be subject to an additional discount if certain pricing increases more than inflation. Medicare is a federal program administered by the federal government that covers individuals age 65 and over as well as those with certain disabilities. Medicare Part D provides coverage to enrolled Medicare patients for self-administered drugs (i.e., drugs that do not need to be administered by a physician). Medicare Part D is administered by private prescription drug plans approved by the U.S. government and each drug plan establishes its own Medicare Part D formulary for prescription drug coverage and pricing, which the drug plan may modify from time-to-time. Medicare Part B covers most injectable drugs given in an in-patient setting, and some drugs administered by a licensed medical provider in hospital outpatient departments and doctors' offices. Medicare Part B is administered by Medicare Administrative Contractors, which generally have the responsibility of making coverage decisions. Subject to certain payment adjustments and limits, Medicare generally pays for Part B covered drugs based on a percentage of manufacturer-reported average sales price. Drug products are subject to discounted pricing when purchased by federal agencies via the Federal Supply Schedule, or FSS. FSS participation is required for a drug product to be covered and paid for by certain federal agencies and for coverage under Medicaid, Medicare Part B and the PHS pharmaceutical pricing program. FSS pricing is negotiated periodically with the Department of Veterans Affairs. FSS pricing is intended to not exceed the price that a manufacturer charges its most-favored non-federal customer for its product. In addition, prices for drugs purchased by the Veterans Administration, Department of Defense (including drugs purchased by military personnel and dependents through the TRICARE retail pharmacy program), Coast Guard, and PHS are subject to a cap on pricing (known as the "federal ceiling price") and may be subject to an additional discount if pricing increases more than inflation. To maintain coverage of drugs under the Medicaid Drug Rebate Program, manufacturers are required to extend discounts to certain purchasers under the PHS pharmaceutical pricing program. Purchasers eligible for discounts include hospitals that serve a disproportionate share of financially needy patients, community health clinics and other entities that receive health services grants from the PHS.

In March 2010, the U.S. Congress enacted the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act, or the Affordable Care Act, which included changes to the coverage and payment for drug products under government health care programs. Since its enactment, there have been judicial and Congressional challenges to numerous elements of the Affordable Care Act, as well as efforts by both the executive and legislative branches of the federal government to repeal or replace certain aspects of the Affordable Care Act. For example, the President signed Executive Orders designed to delay the implementation of certain provisions of the Affordable Care Act or otherwise circumvent some of the requirements for health insurance mandated by the Affordable Care Act. In addition, the U.S. Congress has considered legislation that would repeal or repeal and replace all or part of the Affordable Care Act. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the Affordable Care Act, such as removing penalties, starting January 1, 2019, for not complying with the Affordable Care Act's individual mandate to carry health insurance, delaying the implementation of certain mandated fees, and increasing the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D. In December 2018, a Texas U.S. District Court Judge ruled that the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Cuts and Jobs Act of 2017, or the Tax Act. The Texas U.S. District Court Judge, as well as the presidential administration and the Centers for Medicare and Medicaid Services, or CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, but it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the Affordable Care Act will impact the Affordable Care Act and our business. Any other executive, legislative or judicial action to "repeal and replace" all or part of the Affordable Care Act may have the effect of limiting the amounts that government agencies will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressure, or may lead to significant deregulation, which could make the introduction of competing products and technologies much easier.

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.

Employees

At December 31, 2019, we employed four 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 may be 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, preclinical and clinical development, accounting 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 is expected to increase.

Product and Technology Specific Competition

XCART for B-cell lymphomas

Should any product candidate incorporating the XCART platform technology be approved for use, we will face substantial competition. In addition to the current standard of care for patients, commercial and academic clinical studies are being pursued by a number of parties in the field of immunotherapy. Early results from these studies have fueled continued interest in T-cell immunotherapy. In addition, if approved, our CAR T cell programs would compete with currently marketed drugs and therapies used for treatment of the indications we are addressing, and potentially with drug candidates currently in development for the same indications.

There are currently two CAR T therapies approved in the U.S. and EU: Novartis' Kymriah (tisagenlecleucel) and Gilead Sciences, Inc.'s and Kite Pharma's Yescarta (axicabtagene ciloleucel). However, there are over 100 CAR T therapy products in development with more than 35 being allogeneic and off-the-shelf cell therapies. In addition, depending on the diseases that our CAR T therapies target, we may face competition in the indication of interest from both CAR T therapies and other modalities such as small molecules and antibodies.

T-cell based treatments for cancer, such as CAR T and TCR therapies, have recently been an area of significant research and development by academic institutions and biopharmaceutical companies. XCART therapies may compete with product candidates from a number of companies that are currently focused on this therapeutic modality, which we estimate to include over 20 other companies.

PSA for Drug Delivery

Current competing platforms include PEGylation, Fc-fusion, albumin -fusion, HESylation, PASylation, and CTP-fusion, among others.

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 on, 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 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 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 in 2019 we focused solely on XBIO-101 and the acquisition of XCART. We anticipate that our primary focus will be on advancing the XCART technology through regulatory approval and commercialization and that we will 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;
- Market acceptance of our drug candidates and technologies;
- Costs of acquiring and developing new drug candidates and technologies;
- Ability to bring our drug candidates to market;
- 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, 2019, we had an accumulated deficit of approximately $166.0 million. Substantial doubt exists about our ability to continue as a going concern in the long-term 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.

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.

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, 2019, we had cash of approximately $10.4 million. We expect that we will require additional capital to commence and 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.

If we are unable to obtain funding on a timely basis, we may be required to significantly curtail, delay or discontinue our pre-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.

Risks Related to the Discovery and Development of our Pharmaceutical Products

Our business is substantially dependent on the success of XCART.

Our business will substantially depend on the successful clinical development, regulatory approval and commercialization of the XCART platform technology. It will require substantial clinical development and regulatory approval efforts before we are permitted to commence its commercialization, if ever. We plan to pursue our clinical development strategy through an academic collaboration. If we have difficulty obtaining, or are unable to obtain, and maintaining one or more academic collaborations as planned, we may need to delay, limit or terminate any ongoing or planned clinical development, which would have an adverse effect on our business. The clinical trials and manufacturing and marketing of XCART 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 or identify an academic collaboration partner to continue to fund our research, development and clinical programs, we cannot assure you that XCART or any of our other product candidates will be successfully developed or commercialized.

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, XBIO-101 and, more recently XCART. Our revenues to date consist primarily of collaboration revenue from a single partner and not from product sales. 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 royalty revenue under a sub-license agreement but do not have revenue 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 many 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 CRO's 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 CROs 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.

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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 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 biologic is safe, pure and potent. If these trials or future clinical trials are unsuccessful, our business and reputation could be harmed and our stock price could 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 may not generate significant revenues or become profitable.

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 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 if a regulatory agency 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 the 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 or 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 a significant amount of 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, 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. Our research programs may fail to identify 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, even if we 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, which usually consists of 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 (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. In addition, 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. Further, on October 12, 2017, President Trump issued another executive order requiring the Secretaries of the Departments of Health and Human Services ("HHS"), Labor, and the Treasury to consider proposing regulations or revising existing guidance to allow more employers to form association health plans that would be allowed to provide coverage across state lines, increase the availability of short-term, limited duration health insurance plans, which are generally not subject to the requirements of the ACA, and increase the availability and permitted use of health reimbursement arrangements. On October 13, 2017, the Department of Justice announced that HHS was immediately stopping its cost sharing reduction payments to insurance companies based on the determination that those payments had not been appropriated by Congress. Furthermore, on December 22, 2017, President Trump signed the Tax Cuts and Jobs Act (the "TCJA") into law that, in addition to overhauling the federal tax system, also, effective as of January 1, 2019, repeals the penalties associated with the individual mandate. In part, as a result of the repeal of such penalties, there is litigation pending in various Federal jurisdictions challenging the validity of the ACA and such cases may ultimately be decided by the United States Supreme Court. Congress or the President of the United States also could consider subsequent legislation or executive action to replace or eliminate elements of the ACA. We will continue to evaluate the effect that the ACA and any future measures to modify, repeal or replace the ACA have on our business. We are not able to provide any assurance that the continued healthcare reform debate will not result in legislation, regulation, litigation, or executive action by the President of the United States that is adverse to our business.

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.

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.

We expect to rely on CROs, clinical investigators and clinical study sites to ensure our clinical studies are conducted properly and on time. We will have limited influence over the performance by CROs, clinical investigators and clinical study sites and 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, our 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, 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. For our XCART technology, we intend to seek to leverage the manufacturing expertise and capability of an academic collaborator during early development.

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, including for early XCART development, 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, and/or 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 a significant amount of 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 preclinical 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 any of our current product candidates, 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.

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 enacted and is expected to continue to implement wide-ranging patent reform legislation. Further, certain U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and/or 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 (the "Leahy-Smith Act"), adopted in September 2011, made a number of significant changes to U.S. patent law, the effects of which are still unfolding. 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. 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. 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. The large and rapidly growing market for oncology treatments is likely to attract new entrants. Numerous biotechnology and pharmaceutical companies are focused on developing cancer treatments and I-O technologies including CAR T. 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 preclinical 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 or much 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. We are required to perform periodic impairment reviews of our long-lived assets at least annually. 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. During the third quarter of 2019, we recorded an impairment charge for the full carrying value related to our Goodwill due to a significant decline in our stock price during the period.

We completed our last annual review during the fourth quarter of 2019 and determined that indefinite-lived intangible assets were not impaired as of December 31, 2019. 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 record non-cash charges related to share-based expense, which 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 have limited capital resources and currently have only one full time employee in our finance department. We rely on outside consultants to supplement our internal expertise and 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.

Tax reform may significantly affect the Company and its stockholders.

Due to the potential for changes to tax laws and regulations or changes to the interpretation thereof, the ambiguity of tax laws and regulations, the subjectivity of factual interpretations and other factors, our estimates of effective tax rate and income tax assets and liabilities may be incorrect and our financial statements could be adversely affected. The impact of these factors referenced in the first sentence of this paragraph may be substantially different from period-to-period.

In addition, the amount of income taxes we pay is subject to ongoing audits by U.S. federal, state and local tax authorities and by non-U.S. tax authorities. If audits result in payments or assessments different from our reserves, our future results may include unfavorable adjustments to our tax liabilities and our financial statements could be adversely affected. Any further significant changes to the tax system in the United States or in other jurisdictions (including changes in the taxation of international income as further described below) could adversely affect our financial statements.

Our ability to use potential future operating losses and our federal and state NOL carryforwards to offset taxable income from revenue generated from operations or corporate collaborations could be limited.

The use of our NOL carryforwards may have limitations resulting from certain future ownership changes or other factors under the Code and other taxing authorities. The TCJA changed both the federal deferred tax value of the NOL carryforwards and the rules of utilization of federal NOL carryforwards. The TCJA lowered the corporate tax rate from 35% to 21% effective for our 2018 fiscal year. For NOL carryforwards generated in years prior to 2018, there is no annual limitation on the utilization and the carryforward period remains at 20 years. However, NOL carryforwards generated in years after 2017 will only be available to offset 80% of future taxable income in any single year but will not expire.

If our NOL carryforwards are limited, and we have taxable income which exceeds the available NOL carryforwards for that period, we would incur an income tax liability even though NOL carryforwards may be available in future years prior to their expiration. Any such income tax liability may adversely affect our future cash flow, financial position and financial results.

Our future success depends on our ability to retain principal members of our executive team, consultants and advisors and to attract, retain and motivate qualified personnel.

We are highly dependent on principal members of our executive team, 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, 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, 2019, we had four 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 a 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 Our Common Stock

An active, liquid and orderly market for our Common Stock or Purchase Warrants may not develop.

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

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

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 securities, regardless of our actual operating performance.

The market price of our securities may be volatile. Our securities could be subject to wide fluctuations in price 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 securities by us or our stockholders in the future;
- Adverse economic conditions, including potential adverse effects of public health issues, such as the coronavirus outbreak on economic activity generally; and
- Trading volume of our securities.

Our executive officers, directors and affiliates own a significant percentage of our stock and could exert significant control over matters subject to stockholder approval.

As of March 6, 2020, our executive officers, directors and affiliates beneficially own approximately 19.6% of our outstanding Common Stock. Therefore, these stockholders will have the ability to influence us through their ownership positions. Further, Pharmsynthez has beneficial ownership of approximately 1.0 million shares of Common Stock. These shares represent beneficial ownership of approximately 14.5% of our Common Stock as of March 6, 2020. These stockholders may be able to influence matters requiring stockholder approval.

We have entered into several agreements with our significant stockholders.

We have entered into several agreements with our significant stockholders. Some of the agreement parties may be considered affiliates of ours, which may result in conflicts of interest. In addition, 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.

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 Series A preferred stock is convertible into one-twelfth (1/12) of one share of Common Stock and 1.625 shares of Series B preferred stock are convertible into one share of Common Stock, subject to an Issuable Maximum and subject to certain adjustments, which may cause significant 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, 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.

The issuance of future shares of Common Stock may result in dilution to our stockholders.

As of March 6, 2020, we had approximately 6.3 million shares of Common Stock outstanding, excluding 1.7 million of potentially dilutive Common Stock related to outstanding Preferred Stock, warrants, options, restricted stock and Common Stock awards.

The issuance of these shares of Common Stock and the sale of these shares of Common Stock, or even the potential of such issuance and sale, may have a depressive effect on the market price of our Common Stock and the issuance of such Common Stock will cause dilution to our stockholders.

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.

Certain provisions of our Articles of Incorporation, Bylaws, and the Nevada Revised States may be deemed to have an anti-takeover effect, which could cause the market price of our Common Stock to decline.

Certain provisions of our Articles of Incorporation, Bylaws, and the Nevada Revised States may be deemed to have an anti-takeover effect. Such provisions may delay, deter or prevent a tender offer or takeover attempt that a stockholder might consider to be in that stockholder's best interests, including attempts that might result in a premium over the market price for the shares held by stockholders, which could cause the market price of our Common Stock to decline.

We have, in the past, failed to satisfy certain continued listing requirements on Nasdaq and could fail to satisfy those requirements again in the future which could affect the market price of our Common Stock and liquidity and reduce our ability to raise capital.

Currently, our Common Stock trades on the Nasdaq Capital Market. During 2019, we received notification from Nasdaq informing us of certain listing deficiencies related to the minimum number of publicly held shares required for continued listing. Although we have since cured the deficiency, it is possible that we could fall out of compliance again in the future. If we fail to maintain compliance with any Nasdaq listing requirements, we could be delisted and our stock would be considered a penny stock under regulations of the SEC, and would therefore be subject to rules that impose additional sales practice requirements on broker-dealers who sell our securities. The additional burdens imposed upon broker-dealers by these requirements could discourage broker-dealers from effecting transactions in our Common Stock, which could severely limit the market liquidity of our Common Stock and your ability to sell our securities in the secondary market.

We are a smaller reporting company and the reduced reporting requirements applicable to smaller reporting companies may make our Common Stock less attractive to investors.

We are a smaller reporting company ("SRC"), which allows us to take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not SRCs, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, reduced disclosure obligations regarding executive compensation in our Annual Report and our periodic reports and proxy statements and providing only two years of audited financial statements in our Annual Report and our periodic reports. We will remain an SRC until (a) the aggregate market value of our outstanding Common Stock held by non-affiliates as of the last business day our most recently completed second fiscal quarter exceeds $250 million or (b) (1) we have over $100 million in annual revenues and (2) the aggregate market value of our outstanding Common Stock held by non-affiliates as of the last business day our most recently completed second fiscal quarter exceeds $700 million. We cannot predict whether investors will find our Common Stock less attractive if we rely on certain or all of these exemptions. If some investors find our Common Stock less attractive as a result, there may be a less active trading market for our Common Stock and our stock price may be more volatile and may decline.

ITEM 1B – UNRESOLVED STAFF COMMENTS

Not Applicable.

ITEM 2 – PROPERTIES

We occupy a facility consisting of approximately 1,700 square feet of office space at 40 Speen Street in Framingham, Massachusetts. The sublease is for 21 months through September 2020. 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 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 has extended through November 30, 2020. 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, 2019, that, in the opinion of management, might have a material adverse effect on our financial position, results of operations 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

Our Common Stock is listed for trading on The NASDAQ Capital Market under the symbol "XBIO."

Holders of Record

As of March 6, 2020, there were 425 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

None.

Repurchases of Equity Securities of the Issuer

During 2019 and 2018, 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

We are a biopharmaceutical company focused on advancing XCART™, a personalized Chimeric Antigen Receptor ("CAR") T cell platform technology engineered to target patient-specific tumor neoantigens. The Company is initially advancing cell-based therapeutics targeting the unique B-cell receptor on the surface of an individual patient's malignant tumor cells, for the treatment of B-cell lymphomas. The XCART technology, developed by the Scripps Research Institute in collaboration with the Shemyakin-Ovchinnikov Institute of Bioorganic Chemistry, is believed to have the potential to significantly enhance the safety and efficacy of cell therapy for B-cell lymphomas by generating patient- and tumor-specific CAR T cells. On March 1, 2019, we entered into agreements with Hesperix S.A. ("Hesperix") and Opko Pharmaceuticals LLC to acquire the XCART technology (the "Transaction") and closed the Transaction on July 19, 2019 concurrent with the completion of an approximate $15 million public offering (the "Offering").

The XCART technology platform was designed by its originators to utilize an established screening technique to identify peptide ligands that bind specifically to the unique B-cell receptor ("BCR") on the surface of an individual patient's malignant tumor cells. The peptide is then inserted into the antigen-binding domain of a CAR T cell, and a subsequent transduction/transfection process is used to engineer the patient's T cells into a CAR T format which redirects the patient's T cells to attack the tumor. Essentially, the XCART screening platform is the inverse of a typical CAR T screening protocol wherein libraries of highly specific antibody domains are screened against a given target. In the case of XCART screening, the target is itself an antibody domain, and hence highly specific by its nature. The XCART technology creates the possibility of personalized treatment of lymphomas utilizing a CAR with an antigen-binding domain that should only recognize, and only be recognized by, the unique BCR of a particular patient's B-cell lymphoma. An expected result for XCART is limited off-tumor toxicities, such as B-cell aplasia. Our clinical development program will seek to confirm the early preclinical results, and to demonstrate a more attractive safety profile than existing therapies. We anticipate that our primary focus will now be on advancing this technology through regulatory approval and commercialization.

Additionally, we are leveraging our proprietary drug delivery platform, PolyXen®, by partnering with biotechnology and pharmaceutical companies. PolyXen is an enabling platform technology which can be applied to protein or peptide therapeutics. It employs the natural polymer polysialic acid ("PSA") to prolong a drug's circulating half-life and potentially improve other pharmacological properties. We incorporate our patented and proprietary technologies into a number of drug candidates currently under development with biotechnology and pharmaceutical industry collaborators to create what we believe will be the next-generation biologic drugs with improved pharmacological properties over existing therapeutics.

Our drug candidates have resulted from our research activities or that of our collaborators and are in the development stage. As a result, we continue to commit a significant amount of our 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 United States ("U.S.") by the FDA nor in any other territories by any applicable agencies. We are receiving ongoing royalties pursuant to a license of our PolyXen technology to an industry partner.

We also have oncology therapeutic investigational drug candidate 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. 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 endometrial cancer in conjunction with progesterone therapy. We commenced a Phase 2 trial under an IND in 2017, with first patient dosed in October 2017. We closed patient enrollment in the trial in March 2019 as a result of slower than expected progress on the trial resulting from patient enrollment and retention challenges and have suspended further development of XBIO-101. We currently have no plans to continue development of XBIO-101.

Although we hold a broad patent portfolio, the focus of our internal development efforts in 2019 was limited to winding down the XBIO-101 phase II trial and preliminary development efforts associated with the XCART technology.

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 enter 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.

Effective January 1, 2018, we adopted Accounting Standards Codification ("ASC") Topic 606, *Revenue from Contracts with Customers* ("ASC 606"), using the modified retrospective transition method. Under this method, results for reporting periods beginning after January 1, 2018 are presented under ASC 606, while prior period amounts are not adjusted. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. We did not have any revenue generating contracts with customers and, therefore, the adoption of this new revenue standard did not have a material impact on our consolidated financial statements. Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue at a point in time, or over time, as it satisfies a performance obligation. We only apply the five-step model to contracts when it is probable that it will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, we assess the goods or services promised within each contract, determine those that are performance obligations, and assess whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

As part of the accounting for these arrangements, we must use significant judgment to determine: a) the number of performance obligations based on the determination under step (ii) above; b) the transaction price under step (iii) above; and c) the stand-alone selling price for each performance obligation identified in the contract for the allocation of transaction price in step (iv) above. We use judgment to determine whether milestones or other variable consideration should be included in the transaction price as described further below. The transaction price is allocated to each performance obligation on a relative stand-alone selling price basis, for which we recognize revenue as or when the performance obligations under the contract are satisfied. In developing the stand-alone price for a performance obligation, we consider applicable market conditions and relevant entity-specific factors, including factors that were contemplated in negotiating the agreement with the customer and estimated costs. We validate the stand-alone selling price for performance obligations by evaluating whether changes in the key assumptions used to determine the stand-alone selling prices will have a significant effect on the allocation of transaction price between multiple performance obligations. We recognize a contract asset or liability for the difference between our performance (i.e., the goods or services transferred to the customer) and the customer's performance (i.e., the consideration paid by, and unconditionally due from, the customer).

The terms of our license agreements may 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. We anticipate recognizing non-refundable upfront license payments and development and regulatory milestone payments received by us in license and collaboration arrangements that include future obligations, such as supply obligations, ratably over our expected performance period under each respective arrangement. We make our best estimate of the period over which we expect to fulfil 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.

When we enter into an arrangement to sublicense some of our patents, we will 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 or sublicense 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 it that could change the timing of the revenue recognition. Non-refundable upfront license and sublicense 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.

We expect to recognize 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.

We anticipate reimbursements for research and development services completed by us related to the collaboration agreements to be recognized in operations as revenue on a gross basis.

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 continued performance or future obligations by us are considered inconsequential or perfunctory.

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 Clinical 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.

Share-based Expense

Share-based expense 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.

Share-based 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 the historical volatility of the Company. To the extent Company data is not available for the full expected term of the awards, we use a weighted average of our historical volatility and of a peer group of comparable publicly traded companies over the expected term of the option. The expected term represents the time that options are expected to be outstanding. We account for forfeitures as they occur and not at the time of grant. We have not paid dividends and do not anticipate paying cash dividends in the foreseeable future and, accordingly, we use 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 and settlement 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 generally 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. In June 2018, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2018-07*, Compensation – Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting.* ASU 2018-07 expanded the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. An entity should apply the requirements of Topic 718 to nonemployee awards except for specific guidance on inputs to an option pricing model and the attribution of cost. ASU 2018-07 specifies that Topic 718 applies to all share-based payment transactions in which a grantor acquires goods or services to be used or consumed in a grantor's own operations by issuing share-based payment awards, and that Topic 718 does not apply to share-based payments used to effectively provide (1) financing to the issuer or (2) awards granted in conjunction with selling goods or services to customers as part of a contract accounted for under Topic 606 *Revenue from Contracts with Customers.* ASU 2018-07 was effective for us in the first quarter of fiscal 2019. Adoption of this standard did not have a material impact on our consolidated financial statements. As a result of the adoption of ASU 2018-07, compensation expense related to stock options granted to non-employees is no longer remeasured at each reporting period.

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 granted. Share-based 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 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 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 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.

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

Goodwill and Indefinite-lived Intangible Assets

Assets acquired and liabilities assumed in business combinations, licensing and other transactions are generally recognized at the date of acquisition at their respective fair values. Any excess of the purchase price over the estimated fair values of the net assets acquired is recognized as goodwill. At acquisition, we generally determine the fair value of intangible assets, including in-process research and development ("IPR&D"), using the "income method." This method starts with a forecast of net cash flows, risk adjusted for estimated probabilities of technical and regulatory success (for IPR&D) and adjusted to present value using an appropriate discount rate that reflects the risk associated with the cash flow streams.

Subsequent to acquisition, goodwill and indefinite lived intangibles are not amortized but are tested at least annually as of October 1 for impairment, or when events or changes in circumstances indicate it is more likely than not that the carrying amount of such assets may not be recoverable. Our annual assessment may consist of a qualitative or quantitative analysis to determine if it is more likely than not that its fair value exceeds the carrying value. When performing the qualitative method, we 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 and indefinite lived intangibles are impaired. If we choose to first assess qualitative factors and it is determined that it is not more likely than not that goodwill and intangible assets are impaired, then 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.

When performing quantitative analysis, we use the income and market valuation methods and may weight outcomes of valuation approaches when estimating fair value. Inputs and assumptions used to determine fair value are determined from a market participant view, which might be different than our specific views. The valuation process is complex and requires significant input and judgment using internal and external sources. Market approaches depend on the availability of guideline companies and representative transactions. When using the income approach, complex and judgmental matters applicable to the valuation process may include estimated useful life, projections, tax rates and discount rates.

Goodwill

Goodwill was $0 and approximately $3.3 million at December 31, 2019 and 2018, respectively. We compare the fair value of our reporting unit to its carrying value. An impairment loss, if any, is measured as the excess of the carrying value of goodwill over the fair value of goodwill. 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. During 2018 we used the quantitative method and determined the fair value of Goodwill exceeded its carrying value as of October 1, 2018. We experienced a significant decline in the market price of our stock during 2019 resulting in a drop in our market capitalization indicating potential impairment. The Company determined the fair value of the reporting unit using its market capitalization and concluded that the fair value of the reporting unit was less than the carrying amount in excess of Goodwill. As result, we recorded a Goodwill impairment charge of $3.3 million during the year ended December 31, 2019. There was no impairment recorded during the year ended December 31, 2018.

Indefinite-lived Intangible Assets

Indefinite-lived intangible assets were approximately $9.2 million at December 31, 2019 and 2018, respectively. IPR&D intangible assets are considered indefinite-lived intangible assets until completion or abandonment of the associated research and development efforts. We compare the fair value of the intangible asset to its carrying value. An impairment loss, if any, is measured as the excess of the carrying value of the intangible asset over its fair value. During 2019 and 2018, we used the quantitative method and determined the fair value of the indefinite-lived intangible asset exceeded its carrying value as of October 1, 2019 and 2018.

Intangible assets are highly vulnerable to impairment charges, particularly newly acquired assets for IPR&D. Considering the high risk nature of research and development and the industry's success rate of bringing developmental compounds to market, IPR&D impairment charges are likely to occur in future periods. Estimating the fair value of IPR&D for potential impairment is highly sensitive to changes in projections and assumptions and changes in assumptions could potentially lead to impairment. 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 us 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

We believe our estimates and assumptions are reasonable and otherwise consistent with assumptions that marketplace participants would use in their estimates of fair value. However, if future results are not consistent with our estimates and assumptions, then we may be exposed to an impairment charge, which could be material. 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 indefinite-lived intangible asset impairment tests in 2019 or 2018. We will continue to closely monitor the performance of our indefinite-lived intangible asset. If the business experiences adverse changes in our key assumptions and judgments, we will perform an interim indefinite-lived intangible asset impairment analysis. There can be no assurance that future events will not result in an impairment of our 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 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, 2019 to the year ended December 31, 2018.

Description	2019	2018	Increase	Percentage Change
Revenues:				
Royalty revenue	$ 17,066	$ –	$ 17,066	100.0%
Operating costs and expenses:				
Research and development	(4,889,340)	(2,883,952)	2,005,388	69.5%
General and administrative	(4,731,176)	(4,392,375)	338,801	7.7%
Goodwill impairment	(3,283,379)	–	3,283,379	100.0%
Total operating costs and expenses	(12,903,895)	(7,276,327)	5,627,568	77.3%
Loss from operations	$ (12,886,829)	$ (7,276,327)	$ 5,610,502	77.1%
Other income (expense):				
Other income (expense)	3,315	(24,640)	27,955	113.5%
Interest income, net	108,489	509	107,980	212.1%
Net loss	$ (12,775,025)	$ (7,300,458)	$ 5,474,567	75.0%

Revenue

For the year ended December 31, 2019, revenue represented royalty revenue related to our sublicense agreement with Takeda Pharmaceuticals Co. Ltd. ("Takeda.") Sales of the products related to the treatment of blood and bleeding disorders ("Covered Products") by the sublicensee commenced during the third quarter of 2019 and royalty payments earned on these sales were recorded as revenue by us during the fourth quarter of 2019. We anticipate recognizing these royalty payments as revenue when we can reliably measure them, which is upon receipt of reports from Takeda. As the reported sales are not reliably measurable until we receive notification from Takeda, we expect to recognize revenue from these royalty payments in the quarter after the actual sales of the Covered Products have occurred. We did not receive any license or collaboration service revenue for the year ended December 31, 2018.

Research and Development Expense

Overall, R&D expenses for the year ended December 31, 2019 increased by $2.0 million, or 69.5% to $4.9 million from $2.9 million for the year ended December 31, 2018 primarily due to IPR&D expense of $3.0 million. During the year ended December 31, 2019, we expensed $3.0 million of IPR&D associated with our acquisition of the XCART technology. There was no similar expense in 2018. Excluding the $3.0 million of IPR&D expense from total R&D expense of $4.9 million, R&D expense for the year ended December 31, 2019 was $1.9 million, a decrease of $1.0 million, or 35.6%, from $2.9 million in the comparable period in 2018.

The table below sets forth the research and development expenses incurred by category of expense for the year ended December 31, 2019 and 2018.

	Year ended December 31,	
Category of Expense	**2019**	**2018**
IPR&D expense	$ 3,031,226	$ –
Outside services and Contract Research Organizations	1,357,820	2,242,658
Share-based expense	156,964	203,031
Personnel costs	297,651	280,118
Other	45,679	158,145
Total research and development expense	$ 4,889,340	$ 2,883,952

The decrease in outside services and contract research organizations expense was primarily due to decreased spending on our XBIO-101 phase 2 clinical trial during the year ended December 31, 2019 as compared to same period in the prior year. Costs related to the trial were generally lower as we closed patient enrollment during the first quarter of 2019 and suspended further development of XBIO-101. Share-based expense decreased during the year ended December 31, 2019 as compared to the same period in the prior year primarily due to the revaluation of previously issued warrants to Serum Institute. Other expense decreased during the year ended December 31, 2019 as compared to the same period in the prior year primarily due to lower rent costs as we relocated our corporate headquarters in January 2019.

General and Administrative Expense

G&A expense was $4.7 million for the year ended December 31, 2019, increasing by approximately $0.3 million compared to the same period in the prior year primarily due to $1.1 million of transaction costs associated with the XCART acquisition. There was no similar expense in 2018. Excluding the $1.1 million of transaction costs associated with the XCART acquisition from total G&A expenses of $4.7 million, G&A expense for the year ended December 31, 2019 was $3.6 million, a decrease of $0.8 million, or 17.4%, from $4.4 million in the comparable period in 2018. Payroll and share-based expense decreased due to lower headcount during year ended December 31, 2019 compared to the same period in the prior year, and consulting costs decreased as we reduced spending due to capital constraints. These decreases were partially offset by an increase in investor relations activities during the year ended December 31, 2019 compared to the same period in the prior year.

Goodwill Impairment

Goodwill impairment was $3.3 million for the year ended December 31, 2019 compared to no impairment for the same period in the prior year. During the second half of 2019, we experienced a significant decline in the market price of our stock. As a result, we determined that the fair value of the reporting unit, using our market capitalization, was less than the carrying amount in excess of Goodwill and an impairment charge of $3.3 million was recorded.

Other Income (Expense)

Other income was $3,315 for the year ended December 31, 2019 compared to $24,640 of other expense for the same period in 2018. This decrease in expense was primarily related to a reduction in foreign currency transactions and related changes in foreign currency exchange rates during the year ended December 31, 2019 as compared to the same period in 2018.

Interest Income, net

Interest income, net increased to approximately $108,000 during the year ended December 31, 2019 as compared to $509 in the same period in the prior year. This increase is primarily due to the increase in cash during the year ended December 31, 2019 as compared to the same period in the prior year due to the receipt of net proceeds of $13.4 million from the Offering.

Non-GAAP Measures

In our narrative discussion of operations above, we exclude the impact of our acquisition of the XCART technology from certain operating measures, which narrative discussion includes reconciliation of such adjusted financial measures to the directly comparable U.S. GAAP financial measure. We believe these adjusted operating measures may provide investors with useful information regarding our underlying performance from period to period and allow investors to better understand our results of operations. Management uses these adjusted measures when assessing the performance of the business.

Liquidity and Capital Resources

We incurred a net loss of approximately $12.8 million for the year ended December 31, 2019. We had an accumulated deficit of approximately $166.0 million at December 31, 2019 as compared to an accumulated deficit of approximately $153.2 million at December 31, 2018. Working capital (deficit) was approximately $9.7 million at December 31, 2019 and $(0.4) million at December 31, 2018, respectively. During the year ended December 31, 2019, our working capital increased by $10.1 million due to the Offering and our March 2019 registered direct offering resulting in $16.1 million in combined net proceeds to us. This increase in working capital was partially offset by our net loss for the year ended December 31, 2019. We expect to continue incurring losses for the foreseeable future and may need to raise additional capital or pursue other strategic alternatives in the long-term in order to continue the pursuit of our business plan.

Our principal source of liquidity consists of cash. At December 31, 2019, we had approximately $10.4 million in cash and $1.4 million in current liabilities. At December 31, 2018, we had approximately $0.6 million in cash and $1.6 million in current liabilities.

We have historically relied upon sales of our equity securities to fund our operations. From 2005 until December 31, 2019 we have raised approximately $76.0 million in proceeds from offerings of our common and preferred stock and received approximately $20.0 million from revenue producing activities. More than 90% of the milestone and sublicense revenue received to date has been from a single collaborator, Takeda. We expect the majority of our funding through equity or equity-linked instruments, debt financings, corporate collaborations, related party funding and/or licensing agreements to continue as a trend for the foreseeable future.

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. We believe that we have access to capital resources through possible public or private equity offerings, debt financings, corporate collaborations, related party funding, or other means to continue as a going concern. On March 7, 2019, we closed on a $3.1 million registered direct Common Stock offering resulting in $2.7 million of net proceeds to us. On July 19, 2019, we completed the Offering resulting in approximately $13.4 million of net proceeds to us. We believe that these financings, coupled with our existing resources, will be adequate to fund our operations through mid-2021. However, we anticipate we may need additional capital in the long-term to pursue our business initiatives. 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.

Cash Flows from Operating Activities

Cash flows used in operating activities for the year ended December 31, 2019 totaled approximately $6.4 million, which was primarily due to our net loss for the period, offset by non-cash charges associated with acquired IPR&D, goodwill impairment and share-based expense.

Cash flows used in operating activities for the year ended December 31, 2018 totaled approximately $6.5 million, which was primarily due to our $7.3 million net loss for the period offset by non-cash charges of $1.4 million,

Cash Flows from Investing Activities

Cash flows provided by investing activities for the year ended December 31, 2019 totaled $2,000, which represented proceeds from the sale of property and equipment.

Cash flows provided by investing activities for the year ended December 31, 2018 totaled approximately $23,000 which represented proceeds from the sale of laboratory equipment.

As of December 31, 2019, there were no material commitments for capital expenditures.

Cash Flow from Financing Activities

Cash flows from financing activities for the year ended December 31, 2019 totaled approximately $16.1 million representing net proceeds from our registered direct offering in March 2019 and the Offering in July 2019.

Cash flows from financing activities for the year ended December 31, 2018 totaled approximately $1.5 million representing proceeds from the exercise of warrants.

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 tables represent our contractual obligations as of December 31, 2019, aggregated by type:

	Payments Due by Period As of December 31, 2019				
	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Lease obligations	$ 39,920	$ 39,920	$ –	$ –	$ –
Total	$ 39,920	$ 39,920	$ –	$ –	$ –

Recent Accounting Standards

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

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, 2019 and 2018, and the related consolidated statements of comprehensive loss, stockholders' equity and cash flows for each of the two years in the period ended December 31, 2019**,** 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, 2019 and 2018, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2019, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on 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 26, 2020

XENETIC BIOSCIENCES, INC.
CONSOLIDATED BALANCE SHEETS

	December 31, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash	$ 10,367,920	$ 571,605
Restricted cash	–	66,510
Prepaid expenses and other	722,079	555,856
Total current assets	11,089,999	1,193,971
Property and equipment, net	757	4,956
Goodwill	–	3,283,379
Indefinite-lived intangible assets	9,243,128	9,243,128
Other assets	1,213,042	705,660
Total assets	$ 21,546,926	$ 14,431,094
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 931,128	$ 934,147
Accrued expenses and other current liabilities	484,029	665,641
Total current liabilities	1,415,157	1,599,788
Deferred tax liability	2,918,518	2,918,518
Total liabilities	4,333,675	4,518,306
Commitments and contingent liabilities (Note 13)		
Stockholders' equity:		
Preferred stock, 10,000,000 shares authorized		
Series B, $0.001 par value: 1,804,394 shares issued and outstanding as of December 31, 2019 and December 31, 2018	1,804	1,804
Series A, $0.001 par value: 970,000 shares issued and outstanding as of December 31, 2019 and December 31, 2018	970	970
Common stock, $0.001 par value; 12,500,000 shares authorized as of December 31, 2019 and December 31, 2018; 6,092,432 and 810,856 shares issued as of December 31, 2019 and December 31, 2018, respectively; 6,065,441 and 783,865 shares outstanding as of December 31, 2019 and December 31, 2018, respectively	6,092	811
Additional paid in capital	188,240,451	168,170,244
Accumulated deficit	(166,008,620)	(153,233,595)
Accumulated other comprehensive income	253,734	253,734
Treasury stock	(5,281,180)	(5,281,180)
Total stockholders' equity	17,213,251	9,912,788
Total liabilities and stockholders' equity	$ 21,546,926	$ 14,431,094

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

XENETIC BIOSCIENCES, INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

	FOR THE YEARS ENDED DECEMBER 31,	
	2019	**2018**
Revenue		
Royalty revenue	$ 17,066	$ –
Total revenue	17,066	–
Operating costs and expenses:		
Research and development	(4,889,340)	(2,883,952)
General and administrative	(4,731,176)	(4,392,375)
Goodwill impairment (Note 6)	(3,283,379)	–
Total operating costs and expenses	(12,903,895)	(7,276,327)
Loss from operations	(12,886,829)	(7,276,327)
Other income (expense):		
Other income (expense)	3,315	(24,640)
Interest income, net	108,489	509
Total other income (expense)	111,804	(24,131)
Net loss	(12,775,025)	(7,300,458)
Deemed dividend	(5,284,379)	–
Net loss applicable to common stockholders	$ (18,059,404)	$ (7,300,458)
Basic and diluted loss per share	$ (6.33)	$ (9.66)
Weighted-average shares of common stock outstanding, basic and diluted	2,852,464	756,015

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

XENETIC BIOSCIENCES, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

	Preferred Stock		Common Stock				Accumulated Other		
	Number of Shares	Par Value ($0.001)	Number of Shares	Par Value ($0.001)	Additional Paid in Capital	Accumulated Deficit	Comprehensive Income (Loss)	Treasury Stock	Total Stockholders' Equity
Balance as of January 1, 2018	3,090,742	$ 3,090	753,659	$ 754	$ 165,258,198	$ (145,933,137)	$ 253,734	$ (5,281,180)	$ 14,301,459
Exercise of warrants	–	–	30,834	31	1,479,969	–	–	–	1,480,000
Conversion of Series B preferred stock to shares of common stock	(316,348)	(316)	26,363	26	290	–	–	–	–
Share-based expense	–	–	–	–	1,362,079	–	–	–	1,362,079
Common stock awards to vendors	–	–	–	–	69,708	–	–	–	69,708
Net loss	–	–	–	–	–	(7,300,458)	–	–	(7,300,458)
Balance as of December 31, 2018	2,774,394	$ 2,774	810,856	$ 811	$ 168,170,244	$ (153,233,595)	$ 253,734	$ (5,281,180)	$ 9,912,788
Issuance of common stock and warrants in March 2019 registered direct offering, net of issuance costs	–	–	86,667	87	2,698,963	–	–	–	2,699,050
Issuance of common stock and warrants in July 2019 public offering, net of issuance costs	–	–	1,746,666	1,747	13,420,203	–	–	–	13,421,950
Issuance of common stock in connection with purchase of in-process research and development	–	–	624,995	625	3,030,601	–	–	–	3,031,226
Exercise of pre-funded warrants	–	–	612,417	612	5,597	–	–	–	6,209
Exercise of purchase warrants	–	–	2,201,553	2,202	(2,202)	–	–	–	–
Issuance of common stock to vendor	–	–	7,836	7	(7)	–	–	–	–
Issuance of warrants in connection with reverse stock split	–	–	–	–	63,536	–	–	–	63,536
Issuance of common stock to adjust for reverse split rounding	–	–	1,442	1	(1)	–	–	–	–
Deemed dividend related to Series B Preferred Stock down round provision	–	–	–	–	5,284,379	–	–	–	5,284,379
Accretion of deemed dividend related to Series B Preferred Stock down round provision	–	–	–	–	(5,284,379)	–	–	–	(5,284,379)
Share-based expense	–	–	–	–	806,090	–	–	–	806,090
Common stock awards to vendors	–	–	–	–	47,427	–	–	–	47,427
Net loss	–	–	–	–	–	(12,775,025)	–	–	(12,775,025)
Balance as of December 31, 2019	2,774,394	$ 2,774	6,092,432	$ 6,092	$ 188,240,451	$ (166,008,620)	$ 253,734	$ (5,281,180)	$ 17,213,251

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

XENETIC BIOSCIENCES, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	FOR THE YEARS ENDED DECEMBER 31,	
	2019	**2018**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (12,775,025)	$ (7,300,458)
Adjustments to reconcile net loss to net cash used in operating activities:		
Acquired in-process research and development	3,031,226	–
Goodwill impairment	3,283,379	–
Depreciation	4,199	15,827
Amortization of right of use asset	23,288	–
Gain on sale of property and equipment	(2,000)	(15,437)
Share-based expense	806,090	1,362,079
Vendor share-based payments	47,427	69,708
Issuance of warrants in connection with reverse stock split	63,536	–
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(653,563)	(251,798)
Accounts payable, accrued expenses and other liabilities	(227,961)	(343,878)
Net cash used in operating activities	(6,399,404)	(6,463,957)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceeds from sale of property and equipment	2,000	22,500
Net cash provided by investing activities	2,000	22,500
CASH FLOWS FROM FINANCING ACTIVITIES:		
Net proceeds from issuance of common stock and warrants in July 2019 public offering	13,421,950	–
Net proceeds from issuance of common stock and warrants in March 2019 registered direct offering	2,699,050	–
Proceeds from exercise of warrants	6,209	1,480,000
Net cash provided by financing activities	16,127,209	1,480,000
Net change in cash and restricted cash	9,729,805	(4,961,457)
Cash and restricted cash at beginning of period	638,115	5,599,572
Cash and restricted cash at end of period	$ 10,367,920	$ 638,115
SUPPLEMENTAL CASH FLOW INFORMATION:		
Cash paid for interest	$ 8	$ 599
SUPPLEMENTAL SCHEDULE OF NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Right-of-use assets obtained in exchange for lease obligations	$ 43,330	$ –
Issuance of common stock to vendor	$ 7	$ –
Issuance of common stock to acquire in-process research and development	$ 3,031,226	$ –
Issuance of common stock to adjust for Reverse Stock Split	$ 1	$ –
Issuance of common stock from cashless exercise of purchase warrants	$ 2,202	$ –
Conversion of Series B preferred stock to common stock	$ –	$ 316

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

1. The Company

Background

Xenetic Biosciences, Inc. ("Xenetic" or the "Company"), incorporated in the state of Nevada and based in Framingham, Massachusetts, is a biopharmaceutical company focused on advancing XCART™, a personalized Chimeric Antigen Receptor ("CAR") T cell platform technology engineered to target patient-specific tumor neoantigens. The Company is initially advancing cell-based therapeutics targeting the unique B-cell receptor on the surface of an individual patient's malignant tumor cells, for the treatment of B-cell lymphomas. The XCART technology, developed by the Scripps Research Institute (the "Institute") in collaboration with the Shemyakin-Ovchinnikov Institute of Bioorganic Chemistry ("IBCH"), is believed to have the potential to significantly enhance the safety and efficacy of cell therapy for B-cell lymphomas by generating patient- and tumor-specific CAR T cells. On March 1, 2019, the Company entered into agreements with Hesperix S.A. ("Hesperix") and Opko Pharmaceuticals LLC ("OPKO") to acquire the XCART technology (the "Transaction") and closed the Transaction on July 19, 2019 concurrent with the completion of an approximate $15 million public offering (the "Offering"). For additional information regarding the Transaction, see Note 4 – *Acquisitions*.

Additionally, Xenetic is leveraging its proprietary drug delivery platform, PolyXen®, by partnering with biotechnology and pharmaceutical companies. PolyXen is an enabling platform technology which can be applied to protein or peptide therapeutics. It employs the natural polymer polysialic acid ("PSA") to prolong a drug's circulating half-life and potentially improve other pharmacological properties. Xenetic incorporates its patented and proprietary technologies into a number of drug candidates currently under development 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.

The Company, directly or indirectly, through its wholly-owned subsidiaries, Hesperix and Xenetic Biosciences (U.K.) Limited ("Xenetic UK"), and the wholly-owned subsidiaries of Xenetic UK, Lipoxen Technologies Limited ("Lipoxen"), Xenetic Bioscience, Incorporated and SymbioTec, GmbH ("SymbioTec"), owns various United States ("U.S.") federal trademark registrations and applications, and unregistered trademarks and service marks, including but not limited to XCART, OncoHist™, PolyXen, ErepoXen™, and ImuXen™, which are used throughout this Annual Report. All other company and product names may be trademarks of the respective companies with which they are associated.

Going Concern and Management's Plan

Management evaluates whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the financial statements are issued. The Company has incurred substantial losses since its inception and expects to continue to incur operating losses in the near-term. These factors raise substantial doubt about its ability to 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, related party funding, or other means to continue as a going concern. On March 7, 2019, the Company closed on a $3.1 million registered direct Common Stock offering resulting in $2.7 million of net proceeds to the Company. On July 19, 2019, the Company completed the Offering resulting in $13.4 million of net proceeds to the Company. The Company believes that these financings, coupled with the Company's existing resources, will be adequate to fund the Company's operations through mid-2021. However, the Company anticipates it may need additional capital in the long-term to pursue its business initiatives. 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.

2. Summary of Significant Accounting Policies

Preparation of Financial Statements

On June 25, 2019, the Company effected a reduction, on a 1 for 12 basis, in its authorized Common Stock, par value $0.001, along with a corresponding and proportional decrease in the number of shares issued and outstanding. On the effective date of the reverse stock split, (i) every 12 shares of Common Stock were reduced to one share of Common Stock, with any fractional amounts rounded up to one share; (ii) the number of shares of Common Stock into which each outstanding warrant, restricted stock unit, or option to purchase Common Stock were proportionately reduced on the same basis as the Common Stock; (iii) the exercise price of each outstanding warrant or option to purchase Common Stock were proportionately increased on a 1-to-12 basis; and (iv) the number of shares of Common Stock into which each share of Preferred Stock were proportionately reduced on the same basis as the Common Stock. All of the share numbers, share prices, and exercise prices have been adjusted, on a retroactive basis, to reflect this 1-for-12 reverse stock split.

Certain prior period amounts have been reclassified to conform to the presentation for the current period.

Principles of Consolidation

The consolidated financial statements of the Company include the accounts of Hesperix, Xenetic UK and Xenetic UK's 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

The functional currency for the Company's Switzerland-based subsidiary is the U.S. dollar. The functional currency of the Company's UK-based subsidiaries changed from the British Pound Sterling to the 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 8, *Fair Value Measurements*, for discussion of the Company's fair value measurements.

Cash

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, 2018 restricted cash represented a certificate of deposit that secured the Company's outstanding letter of credit of approximately $0.1 million for its former operating lease in Lexington, Massachusetts (the "Lexington Lease"). The Lexington Lease expired in January 2019 and the letter of credit terminated in May 2019.

The following table provides a reconciliation of cash and restricted cash reported in the consolidated balance sheets to the total of the amounts in the consolidated statement of cash flows:

	December 31, 2019	December 31, 2018
Cash	$ 10,367,920	$ 571,605
Restricted cash	–	66,510
Total cash and restricted cash in the statement of cash flows	$ 10,367,920	$ 638,115

Concentration of Credit Risk

Financial instruments that subject the Company to concentrations of credit risk include cash. The Company maintains cash with various major financial institutions that management believes are of high credit quality.

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. At acquisition, we generally determine the fair value of intangible assets, including IPR&D, using the "income method." IPR&D intangible assets are considered indefinite-lived intangible assets and are not amortized 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.

IPR&D is not amortized but is reviewed 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 orcircumstances 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.

The impairment loss, if any, is measured as the excess of the carrying value of the intangible asset over its fair value. During 2019 and 2018, we used the quantitative method and determined that the fair value of the indefinite-lived intangible assets exceeded its carrying value as October 1, 2019 and 2018.

Intangible assets are highly vulnerable to impairment charges, particularly newly acquired assets for IPR&D. Considering the high risk nature of research and development and the industry's success rate of bringing developmental compounds to market, IPR&D impairment charges are likely to occur in future periods. Estimating the fair value of IPR&D for potential impairment is highly sensitive to changes in projections and assumptions and changes to assumptions could potentially lead to impairment. The Company's estimates and assumptions are reasonable and otherwise consistent with assumptions market participants would use in their estimates of fair value. However, if future results are not consistent with the Company's estimates and assumptions, then we may be exposed to an impairment charge, which could be material. Use of different estimates and judgments could yield materially different results in our analysis and could result in materially different asset values or expense.

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 historically had performed its annual impairment review as of October 1 at the reporting unit level. Goodwill may be considered impaired if the carrying value of the reporting unit, including goodwill, exceeds the reporting unit's fair value. The Company is comprised of one reporting unit. The Company determined that Goodwill was impaired during the year ended December 31, 2019. See Note 6 *Goodwill, Indefinite-Lived Intangible Assets and Other Long-term Assets*.

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, 2019 and 2018.

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.

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.

Effective January 1, 2018, the Company adopted Accounting Standards Codification ("ASC") Topic 606, *Revenue from Contracts with Customers* ("ASC 606"), using the modified retrospective transition method. Under this method, results for reporting periods beginning after January 1, 2018 are presented under ASC 606, while prior period amounts are not adjusted. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. The Company did not have any revenue generating contracts with customers and, therefore, the adoption of this new revenue standard did not have a material impact on the consolidated financial statements. Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue at a point in time, or over time, as it satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that it will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract, determine those that are performance obligations, and assess whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

As part of the accounting for these arrangements, the Company must use significant judgment to determine: a) the number of performance obligations based on the determination under step (ii) above; b) the transaction price under step (iii) above; and c) the stand-alone selling price for each performance obligation identified in the contract for the allocation of transaction price in step (iv) above. The Company uses judgment to determine whether milestones or other variable consideration should be included in the transaction price as described further below. The transaction price is allocated to each performance obligation on a relative stand-alone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied. In developing the stand-alone price for a performance obligation, the Company considers applicable market conditions and relevant entity-specific factors, including factors that were contemplated in negotiating the agreement with the customer and estimated costs. The Company validates the stand-alone selling price for performance obligations by evaluating whether changes in the key assumptions used to determine the stand-alone selling prices will have a significant effect on the allocation of transaction price between multiple performance obligations. The Company recognizes a contract asset or liability for the difference between the Company's performance (i.e., the goods or services transferred to the customer) and the customer's performance (i.e., the consideration paid by, and unconditionally due from, the customer).

The terms of the Company's license agreements may 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. The Company anticipates recognizing 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, 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 fulfill 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 the Company enters into an arrangement to sublicense some of its patents, it will consider the performance obligations to determine if there is a single element or multiple elements to the arrangement as it determines the proper method and timing of revenue recognition. The Company considers the terms of the license or sublicense for such elements as price adjustments or refund clauses in addition to any performance obligations for it 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 it that could change the timing of the revenue recognition. Non-refundable upfront license and sublicense 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.

The Company anticipates reimbursements for research and development services completed by the Company related to the collaboration agreements to be 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 3, *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 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 makes 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, 2019 and 2018, the Company has recorded accrued program expense of approximately $0.1 million and $0.2 million, respectively, as a component of accrued expenses. In addition, the Company has recorded approximately $0.7 million of deposits held with our clinical trial vendors as a component of prepaid expenses and other current assets as of December 31, 2019 and 2018.

Share-based Expense

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 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 the historical volatility of the Company. To the extent Company data is not available for the full expected term of the awards the Company uses a weighted-average of the historical volatility of the Company and of a peer group of comparable publicly traded 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 and settlement 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. In June 2018, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2018-07*, Compensation – Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting.* ASU 2018-07 expanded the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. An entity should apply the requirements of Topic 718 to nonemployee awards except for specific guidance on inputs to an option pricing model and the attribution of cost. ASU 2018-07 specifies that Topic 718 applies to all share-based payment transactions in which a grantor acquires goods or services to be used or consumed in a grantor's own operations by issuing share-based payment awards, and that Topic 718 does not apply to share-based payments used to effectively provide (1) financing to the issuer or (2) awards granted in conjunction with selling goods or services to customers as part of a contract accounted for under Topic 606 *Revenue from Contracts with Customers.* ASU 2018-07 was effective for the Company in the first quarter of fiscal 2019. Adoption of this standard did not have a material impact on the Company's consolidated financial statements. As a result of the adoption of ASU 2018-07, compensation expense related to stock options granted to non-employees is no longer remeasured at each reporting period.

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, as this provides the most reliable measure of the fair value of the awards granted. 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 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. Warrants granted in connection with ongoing arrangements are more fully described in Note 10, *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, 2019 and 2018, there were approximately 27,000 JSOP awards issued.

For the years ended December 31, 2019 and 2018, 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, 2019 and 2018, approximately 516,000 and 65,000 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.

Leases

The Company leases administrative facilities under operating leases. Lease agreements may include rent holidays, rent escalation clauses and tenant improvement allowances. In February 2016, FASB issued ASU 2016-02, *Leases (Topic 842)*. ASU 2016-02 requires 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. Subsequently, in July 2018, the FASB issued ASU 2018-11, Lease (Topic 842): Targeted Improvements, which provides a number of practical expedients in transition. The Company adopted ASU 2016-02 effective January 1, 2019 and elected a package of practical expedients and the new transition approach permitted by ASU 2018-11. ASU 2018-11 allows the Company not to reassess existing identification of a lease, classification of a lease or any initial direct costs. The Company has also elected to use the hindsight practical expedients. The adoption did not have a material impact on the Company's consolidated financial statements, resulted in an approximate $43,000 increase in total assets and total liabilities in our consolidated balance sheet and did not have any effect on our accumulated deficit at the beginning of 2019. See Note 13, *Commitments and Contingent Liabilities* for further information.

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 November 2018, the FASB issued ASU 2018-18, *Clarifying the Interaction between Topic 808 and Topic 606* . The guidance clarifies that certain transactions between collaborative arrangement participants should be accounted for as revenue under ASC 606 when the collaborative arrangement participant is a customer for a promised good or service that is distinct within the collaborative arrangement. The guidance also precludes entities from presenting amounts related to transactions with a collaborative arrangement participant that is not a customer as revenue, unless those transactions are directly related to third-party sales. ASU 2018-18 is effective in the first quarter of 2020 and should be applied retrospectively to January 1, 2018, when we adopted ASC 606. Early adoption is permitted. We are evaluating the effect of adoption, but we do not expect a material effect on our revenue.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*. The guidance modifies the measurement and recognition of credit losses for most financial assets and certain other instruments. The amendment updates the guidance for measuring and recording credit losses on financial assets measured at amortized cost by replacing the "incurred loss" model with an "expected loss" model. This may result in earlier recognition of allowance for losses. ASU 2016-13 is effective for public entities for fiscal years beginning after December 15, 2019 but early adoption is permitted. We are currently evaluating the impact of adoption, but we do not anticipate that it will have a material effect on our consolidated financial statements.

3. Significant Strategic Drug Development Collaborations – Related Parties

Takeda Pharmaceutical Co. Ltd., ("Takeda") (formerly 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 Takeda, related to the development of a novel series of polysialylated blood coagulation factors. Takeda acquired Shire plc in January 2019. This collaboration with Takeda relies on the Company's PolyXen technology to conjugate PSA with therapeutic blood-clotting factors, with the goal of improving the pharmacokinetic profile and extending the active half-life of these biologic molecules. The agreement grants Takeda a worldwide, exclusive, royalty-bearing license to the Company's PSA patented and proprietary technology in combination with Takeda's proprietary molecules designed for the treatment of blood and bleeding disorders.

On October 27, 2017, the Company entered into a Right of Sublicense Agreement (the "Sublicense Agreement") with Baxalta Incorporated, Baxalta US Inc., and Baxalta GmbH (collectively, with their affiliates, "Baxalta") wholly-owned subsidiaries of Takeda. 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 in connection with products related to the treatment of blood and bleeding disorders ("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.

In November 2019 the Company was notified by Takeda that net sales of the Covered Products by the sublicensee commenced during the third quarter of 2019 and, as a result, royalty payments were expected to be paid to the Company under the Sublicense Agreement. The Company's policy is 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. As the reported sales were not reliably measurable until the Company received notification from Takeda, the Company recognized $17,000 in royalty revenue during the fourth quarter of 2019. There were no remaining performance obligations and all other revenue recognition criteria were met.

SynBio LLC

In August 2011, SynBio LLC ("SynBio"), a wholly-owned subsidiary of Pharmsynthez, and the Company entered into a stock subscription and collaborative development agreement (the "Co-Development Agreement"). The Company granted an exclusive license to SynBio to develop, market and commercialize certain drug candidates utilizing molecules based on SynBio's technology and the Company's proprietary technologies (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 preclinical 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, 2019, 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, 2019 and 2018.

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 preclinical 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, 2019, 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, 2019 and 2018.

Serum Institute had a share ownership of approximately 0.9% and 6.7% of the total issued Common Stock of the Company as of December 31, 2019 and 2018, respectively. In addition to its' Common Stock ownership, Serum Institute holds outstanding warrants to purchase the Company's Common Stock. See Note 10, *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 product 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 preclinical 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.

Pharmsynthez is an affiliate and former controlling stockholder of the Company with a share ownership of approximately 7.4% and 57.1% of the total outstanding Common Stock of the Company as of December 31, 2019 and 2018, 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 outstanding Series B Preferred Stock, and all of the Company's outstanding Series A Preferred Stock through its wholly-owned subsidiary, SynBio, as of December 31, 2019 and 2018. See Note 10, *Stockholders' Equity*.

4. Acquisitions

On March 1, 2019 (the "Signing Date") the Company entered into agreements with Hesperix and OPKO to acquire the XCART technology. The Company entered into a Share Purchase Agreement, as amended (the "Share Purchase Agreement"), with Hesperix, the owners of Hesperix (each, a "Seller" and collectively, the "Sellers"), and Alexey Andreevich Vinogradov, as the representative of each Seller, pursuant to which the Company purchased from Sellers all of the issued and outstanding shares of capital stock of Hesperix.

Under the terms of the Share Purchase Agreement, the Company issued to Sellers an aggregate of Four Hundred Six Thousand Two Hundred Forty-Six (406,246) shares of the Company's Common Stock (the "Transaction Shares") at the time of the closing. In addition, the Share Purchase Agreement contains customary representations and warranties relating to each Seller and about the condition of the Company and Hesperix. The Company issued the Transaction Shares pursuant to a registration statement on Form S-4.

On the Signing Date and in connection with the Transaction, Hesperix entered into an assignment agreement (the "Hesperix Assignment Agreement") with IBCH, Pharmsynthez, and certain other parties thereto (collectively, the "Assignors"), pursuant to which, the Assignors have agreed, among other things, to sell, assign, transfer, and convey unto Hesperix all of their individual right, title, and interest throughout the world in and to patents related to "Articles And Methods Directed To Personalized Therapy Of Cancer," and the related know-how. Hesperix has agreed to pay each of IBCH and Pharmsynthez a royalty rate in the low single digit range based on the net sales of products in each country in which, in the absence of the Hesperix Assignment Agreement, the manufacture, use, offer for sale, sale, or importation of such product would infringe a valid claim of a patent.

Also on the Signing Date, the Company entered into an assignment agreement with OPKO (the "OPKO Assignment Agreement"), pursuant to which the Company will acquire and accept, all of OPKO's right, title and interest in and to that certain Intellectual Property License Agreement (the "IP License Agreement"), entered into between the Institute and OPKO regarding certain patents related to "Articles And Methods Directed To Personalized Therapy Of Cancer" and in which the Institute agreed to grant an exclusive royalty-bearing license, to the patent rights owned by the Institute to OPKO, and OPKO has agreed to pay the Institute a royalty rate in the low single digit range based on the net sales of products in each country in which, in the absence of the IP License Agreement, the manufacture, use, offer for sale, sale, or importation of such product would infringe a valid claim of a patent or pending application.

Under the terms of the OPKO Assignment Agreement and the IP License Agreement, the Company issued One Hundred Sixty Four Thousand Sixty Two (164,062) shares of the Company's Common Stock to OPKO and Fifty-Four Thousand Six Hundred Eighty Seven (54,687) shares of the Company's Common Stock to the Institute at the time of the closing. In addition, the OPKO Assignment Agreement contains customary representations and warranties relating to OPKO and the IP License Agreement.

On July 19, 2019, the Company closed the Transaction (the "Closing Date"), acquiring IPR&D related to certain intellectual property rights with respect to the XCART technology. The acquisition did not meet the business combination requirements and, as a result, was accounted for as an asset acquisition. The total consideration for the IPR&D was approximately $4.1 million, which represented the value of the common shares issued of $3.0 million utilizing the market price of the Company's stock price at the Closing Date and approximately $1.1 million of transaction costs. As there was no future alternative use for the IPR&D, the Company recorded expense of $3.0 million to research and development expense and $1.1 million to general and administrative expense for the transaction costs in the year ended December 31, 2019.

5. Property and Equipment, net

Property and equipment, net consists of the following:

	December 31, 2019	December 31, 2018
Office and computer equipment	$ 42,289	$ 42,289
Leasehold improvements	–	26,841
Furniture and fixtures	14,738	20,263
Property and equipment – at cost	57,027	89,393
Less accumulated depreciation	(56,270)	(84,437)
Property and equipment, net	$ 757	$ 4,956

Depreciation expense was approximately $4,000 and $16,000 for the years ended December 31, 2019 and 2018, respectively. During the year ended December 31, 2019, the Company sold certain furniture and fixtures for $2,000 resulting in an approximate $2,000 gain. During the year ended December 31, 2018, the Company sold certain laboratory equipment for $22,500 resulting in an approximate $15,000 gain.

6. Goodwill, Indefinite-Lived Intangible Assets and Other Long-Term Assets

Goodwill

The Company experienced a significant decline in the market price of its stock during 2019 resulting in a drop in its market capitalization indicating potential impairment. The Company determined the fair value of the reporting unit using its market capitalization, concluding that the fair value of the reporting unit was less than the carrying amount in excess of Goodwill. As a result, the Company recorded a $3.3 million impairment charge during the year ended December 31, 2019, which is presented within operating costs and expenses in the consolidated statements of comprehensive loss. A reconciliation of the change in the carrying value of goodwill is as follows:

Balance as of January 1, 2018	$ 3,283,379
No changes	–
Balance as of December 31, 2018	$ 3,283,379
Impairment	(3,283,379)
Balance as of December 31, 2019	$ –

Indefinite-Lived Intangible Assets

The Company's indefinite-lived intangible asset, OncoHist, is IPR&D relating to the Company's business combination with SymbioTec in 2012. The carrying value of the IPR&D was approximately $9.2 million as of December 31, 2019 and 2018. No impairment was recorded during the years ended December 31, 2019 and 2018. The IPR&D is not yet commercialized and, therefore, has not yet begun to be amortized as of December 31, 2019.

Other Long-Term Assets

The Company entered into an agreement with Serum Institute for the prepayment of clinical PSA supply in exchange for Company Common Stock. As of December 31, 2019 and 2018, the Company has classified $0.7 million of prepaid clinical supply as long-term as it does not anticipate utilizing the majority of the PSA supply within the next 12 months. No clinical supply was utilized during the years ended December 31, 2019 and 2018.

In October 2019, the Company entered into a Loan Agreement with Pharmsynthez (the "Pharmsynthez Loan"), pursuant to which the Company advanced Pharmsynthez an aggregate principal amount of up to $500,000 to be used for the development of a specific product under the Co-Development Agreement. The Pharmsynthez Loan has a term of 15-months and accrues interest at a rate of 10% per annum. The Pharmsynthez Loan is guaranteed by all of the operating subsidiaries of Pharmsynthez, including SynBio and AS Kevelt, and is secured by all of the equity interests of the Company owned by Pharmsynthez and SynBio. The Company recognized approximately $9,000 of interest income related to this loan during the twelve-months ended December 31, 2019.

7. Accrued Expenses

Accrued expenses consist of the following:

	December 31, 2019	December 31, 2018
Accrued payroll and benefits	$ 68,016	$ 53,541
Accrued professional fees	306,413	394,075
Accrued research costs	80,519	205,067
Other	9,039	11,346
	$ 463,987	$ 664,029

8. 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 carrying amount of certain of the Company's financial instruments approximate fair value due to their short maturities. There were no financial instruments classified as Level 3 in the fair value hierarchy during the years ended December 31, 2019 and 2018.

9. 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,	
	2019	2018
Domestic (U.S.)	$ (4,317,585)	$ (3,824,673)
Foreign (U.K.)	(2,302,131)	(3,379,268)
Foreign (Germany)	(3,389,473)	(96,517)
Foreign (Switzerland)	(2,765,836)	–
Loss before income taxes	$ (12,775,025)	$ (7,300,458)

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,	
	2019	2018
Federal	$ (2,682,755)	$ (1,533,096)
State	(284,724)	(238,952)
Increase in tax losses not recognized	1,878,033	1,695,482
Permanent differences, net	1,323	40,015
Goodwill impairment	689,510	–
Foreign rate differential	381,190	124,294
Share-based payments, net	11,084	20,441
Enhanced research and development tax credits	(54,148)	(108,184)
Other items	60,487	–
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,	
	2019	2018
Deferred tax assets:		
U.K. net operating loss carryforwards	$ 8,984,851	$ 8,039,343
U.K. capital loss carryforwards	1,340,302	1,298,303
U.S. federal net operating loss carryforwards	3,857,973	3,184,691
Switzerland net operating loss carryforwards	23,510	–
IPR&D	6,454,240	6,108,078
Share-based payments	2,065,735	1,859,357
Enhanced research and development tax credits	1,219,815	1,109,026
Germany net operating loss carryforwards	545,852	524,093
U.S. state net operating loss carryforwards	1,160,983	1,298,745
Transaction costs	142,013	–
Accrued expenses	72,503	59,979
Depreciation	5,070	3,283
Lease liability	5,475	–
Total deferred tax assets before valuation allowance	25,878,322	23,484,898
Valuation allowance for deferred tax assets	(25,872,847)	(23,484,898)
Net deferred tax assets	5,475	–
Deferred tax liabilities:		
Indefinite-lived intangible asset	(2,918,518)	(2,918,518)
Right of use asset – leases	(5,475)	–
Total deferred tax liabilities	(2,923,993)	(2,918,518)
Net deferred liability	$ (2,918,518)	$ (2,918,518)

For the years ended December 31, 2019 and 2018, the Company had U.K. net operating loss carryforwards of approximately $52.9 million and $47.3 million, respectively, U.S. federal net operating loss carryforwards of approximately $18.4 million and $16.5 million, respectively, U.S. state net operating loss carryforwards of approximately $18.4 million and $16.2 million, respectively, Germany net operating loss carryforwards of approximately $1.7 million and $1.7 million, respectively, and Switzerland net operating loss carryforwards of approximately $0.3 million and $0 million, respectively. The U.K. and Germany net operating loss carryforwards can be carried forward indefinitely. $5.0 million of the U.S. federal net operating loss carryforwards can be carried forward indefinitely and the remaining 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 U.S. Internal Revenue Code (the "Code"). These restrictions may limit the future use of the operating loss carryforwards and tax credits if certain ownership changes described in the 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 and Switzerland are also subject to restrictions under German and Swiss 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.

As of December 31, 2019 and 2018, the Company did not record any uncertain tax positions.

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 2014 through 2019 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, 2019. 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 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, 2019, 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.

10. Stockholders' Equity

The Offering

On July 17, 2019, the Company entered into an underwriting agreement (the "Underwriting Agreement") with Maxim Group LLC (the "Underwriter"), relating to the Company's Offering of 1,730,000 shares (the "Shares") of the Company's common stock, par value $0.001 (the "Common Stock"), Prefunded Warrants to purchase 570,000 shares of Common Stock (the "Prefunded Warrants"), and warrants to purchase 2,300,000 shares of the Common Stock (the "Purchase Warrants," and together with the Shares and the Prefunded Warrants, the "Firm Securities"). Each Share was sold together with one Purchase Warrant at a combined public offering price of $6.50 per Share and Purchase Warrant. Each Prefunded Warrant purchased was sold together with one Purchase Warrant at a combined public offering price of $6.49 per Prefunded Warrant and Purchase Warrant. The Prefunded Warrants were exercisable beginning on July 17, 2019 at an exercise price of $0.01 per share. The holders of the Prefunded Warrants did not have the right to exercise any portion of the Prefunded Warrant if the holder (together with its affiliates) would beneficially own in excess of 4.99% of the number of shares of our Common Stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Prefunded Warrants. The Prefunded Warrants had an intrinsic value of approximately $3.1 million. Pursuant to the Underwriting Agreement, the Company also granted the Underwriter a 45-day option to purchase up to an additional 345,000 shares of Common Stock and/or Purchase Warrants to purchase up to 345,000 shares of Common Stock (the "Additional Securities," and together with the Firm Securities, the "Securities"), at the public offering price less discounts and commissions. The Securities were offered, issued, and sold pursuant to an effective Registration Statement on Form S-1 (Reg. No. 333-231508) and accompanying prospectus filed with the SEC under the Securities Act of 1933, as amended.

On the Closing Date, the Company completed the Offering resulting in gross proceeds to the Company of approximately $15.0 million before deducting the underwriting discount and offering fees and expenses payable by the Company. In addition, on the Closing Date, the Underwriter exercised its overallotment option with respect to 160,000 Purchase Warrants, resulting in additional gross proceeds of $1,600. The Company intends to use the net proceeds from the Offering of approximately $13.4 million to fund its research, development and clinical programs, including the development of the XCART technology acquired in the Transaction, and for other general corporate purposes. All of the Prefunded Warrants were exercised during the year ended December 31, 2019 resulting in $5,700 of net proceeds to the Company.

The Purchase Warrants are immediately exercisable at a price of $13.00 per share of Common Stock and expire five years from the date of issuance. The Purchase Warrants began trading on NASDAQ on July 23, 2019 under the symbol "XBIOW." The Purchase Warrants also provide that if the weighted-average price of Common Stock on any trading day on or after 30 days after issuance is lower than the then-applicable exercise price per share, each Purchase Warrant may be exercised, at the option of the holder, on a cashless basis for one share of Common Stock. The Company evaluated the terms of the warrants issued and determined that they should be classified as equity instruments. The grant date fair value of these warrants was estimated to be $4.61 per share, for a total of approximately $11.3 million. The fair value of these warrants was estimated using a Black-Scholes model utilizing the following key valuation assumptions: the Company's stock price, a risk free rate of 1.83%, an expected life of 5 years and an expected volatility of 141.89%. Purchase Warrants to purchase approximately 2.2 million shares of Common Stock were exercised on a cashless one-for-one basis during the year ended December 31, 2019.

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.

On July 16, 2019, the Company, in connection with the Offering, entered into a consent agreement with certain holders of warrants to purchase shares of the Company's Common Stock whose consent was sought in connection with the Offering. In consideration of the holders' consent, the Company agreed to (i) issue such holders an aggregate of 16,666 shares of the Company's Common Stock ("Consent Shares") and (ii) adjust the exercise price of those certain warrants issued to each holder in connection with the Company's Reverse Stock Split on June 25, 2019. The Consent Shares and incremental cost associated with the warrant modification were determined to be direct costs of the Offering and, as a result, have been included within net proceeds from the Offering.

On June 21, 2019, the Company filed a Certificate of Change to the Company's Articles of Incorporation with the Secretary of State of Nevada to effect the Reverse Stock Split. The Reverse Stock Split was effective at 12:01 a.m., eastern Time, on June 25, 2019. No fractional shares were issued as a result of the Reverse Stock Split and any remaining share fractions were rounded up to the nearest whole share, resulting in 1,442 new shares of Common Stock being issued to existing holders of the Company's Common Stock.

On June 19, 2019, shareholders of the Company voted to approve an amendment to the Company's Articles of Incorporation to increase the authorized shares of Common Stock to 150,000,000 shares on a pre-Reverse Stock Split basis (the "Authorized Share Increase"). On June 24, 2019, the Company filed a Certificate of Amendment to the Company's Articles of Incorporation with the Secretary of the State of Nevada to effect the Authorized Share Increase as of June 25, 2019. As a result of the Authorized Share Increase and after giving effect to the Reverse Stock Split, the Company had 12,500,000 authorized shares of Common Stock.

As a result of the Reverse Stock Split, the number of outstanding shares of our Common Stock held by non-affiliates was approximately 475,000. On June 28, 2019, the Company received a notice from the Nasdaq Capital Market ("NASDAQ") that it no longer met the minimum 500,000 publicly held shares requirement for continued listing. On July 19, 2019, the Company received a notice from NASDAQ that the Company had regained compliance with the publicly held shares requirement as a result of the Offering.

On March 5, 2019, the Company entered into a Securities Purchase Agreement with certain purchasers pursuant to which the Company offered to the purchasers, in a registered direct offering, an aggregate of (i) 86,667 shares of Common Stock, par value $0.001 per share and (ii) prefunded warrants to purchase 42,417 shares of Common Stock. The prefunded warrants were exercisable beginning on March 7, 2019 at an exercise price of $0.012 per share. The shares were sold at a price of $24.00 per share and the prefunded warrants were sold at a price of $23.988 per prefunded warrant, which represents the per share purchase price for the shares less the $0.012 per share exercise price for each such prefunded warrant. The holders of the prefunded warrants did not have the right to exercise any portion of the prefunded warrant if the holder (together with its affiliates) would beneficially own in excess of 9.99% of the number of shares of our Common Stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the prefunded warrants. The net proceeds to the Company from this offering were approximately $2.7 million, after deducting expenses related to the offering, including dealer-manager fees and expenses. In a concurrent private placement, the Company issued to the purchasers a warrant to purchase one share of the Company's Common Stock for each share and prefunded warrant purchased in the offering. These warrants have an exercise price of $27.00 per share, were exercisable beginning on September 8, 2019 and expire seven years from such date. The Company evaluated the terms of the warrants issued and determined that they should be classified as equity instruments. The grant date fair value of these warrants was estimated to be $22.74 per share, for a total of approximately $2.9 million. The fair value of the warrants was estimated using a Black-Scholes model utilizing the following key valuation assumptions: the Company's stock price, a risk free rate of 2.56%, an expected life of 7.5 years and an expected volatility of 111.3%. The prefunded warrants had an intrinsic value of approximately $1.1 million. During the year ended December 31, 2019, all of the prefunded warrants were exercised resulting in $509 of net proceeds to the Company.

The holders of Series B Preferred Stock converted approximately 316,000 shares into approximately 26,000 shares of Common Stock during the year ended December 31, 2018. There were no conversions during the year ended December 31, 2019.

During the year ended December 31, 2018, approximately 31,000 warrants were exercised resulting in the issuance of approximately 31,000 shares of Common Stock. There were no exercises of warrants during the year ended December 31, 2019.

Series A Preferred Stock

The Company has designated 1,000,000 shares as Series A preferred stock with each share having a par value of $0.001 and stated value of $4.80 (the "Series A Preferred Stock"). 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 therefor. 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. 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 on a twelve preferred shares for one share of Common Stock basis.

Redemption. 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 twelve shares of Series A Preferred Stock to one share of Common Stock.

The Series A Preferred Stock has additional terms covering stock dividends and splits, voting rights, fractional shares and fundamental transactions. As of December 31, 2019 and 2018, there were approximately 1.0 million shares of Series A Preferred Stock issued and outstanding which are convertible into approximately 80,834 shares of Common Stock.

Series B Preferred Stock

The Company has designated 2,500,000 shares as Series B preferred stock with each share having a stated value of $4.00 per share (the "Series B Preferred Stock"). 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. Series B Preferred Stock is convertible, at any time and from time to time at the option of the holder thereof on a 1.625 preferred shares to one common share basis, subject to an issuable maximum and the adjustments described below.

Subsequent Equity Sales. The Series B Preferred Stock has full ratchet price based anti-dilution protection, subject to 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. There is no bifurcation of the embedded conversion option being clearly and closely related to the host instrument.

The Series B Preferred Stock has additional terms covering stock dividends and splits, voting rights, fractional shares and fundamental transactions. As of December 31, 2019 and 2018, there were approximately 1.8 million shares of Series B Preferred Stock issued and outstanding which are convertible into approximately 0.6 million and 0.3 million shares of Common Stock, respectively. As of December 31, 2019, the issuable maximum is 0.6 million shares of Commons Stock that can be issued upon the conversion of the currently outstanding Series B Preferred Stock and the exercise of outstanding warrants that were issued in connection with the Series B Preferred Stock. The holders of Series B Preferred Stock converted approximately 0.3 million shares into approximately 26,000 shares of Common Stock during the year ended December 31, 2018. There were no Series B Preferred Stock conversions during the year ended December 31, 2019.

The March 2019 registered direct offering triggered the down-round provision in the Company's Series B Preferred Stock resulting in an adjustment to the conversion ratio and the recording of a deemed dividend of $3.9 million increasing the net loss attributable to common shareholders for year ended December 31, 2019. In addition, the Offering triggered the down-round provision in the Company's Series B Preferred Stock, resulting in a further adjustment to the conversion ratio and the recording of an additional deemed dividend of $1.4 million increasing the net loss attributable to common shareholders for the year ended December 31, 2019.

Warrants Related to Collaboration and Consulting Agreements

In connection with certain of the Company's collaboration agreements and consulting arrangements, the Company has issued warrants to purchase shares of Common Stock as payment for services. As of December 31, 2019 and 2018, warrants to purchase 32,412 and 44,944 shares of Common Stock were outstanding, respectively. The fair value of these warrants was determined at each 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 17,033 new shares of Common Stock at an exercise price of $304.92 per share ("SynBio 2014 Warrant"). The SynBio 2014 Warrant was exercisable in four equal tranches, each with separate non-market, performance-based vesting criteria. The Company used its judgment to assess the probability and timing of SynBio achieving these vesting criteria and estimated that it was not probable that the vesting criteria for any tranche would be achieved. None of the vesting criteria were met and, therefore, these warrants were forfeited. As a result, the Company did not recognize expense related to this warrant during the years ended December 31, 2019 and 2018.

In connection with the SynBio 2014 Warrant grant, warrants to purchase 809 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 vesting criteria for any tranche were not met and, therefore, these warrants were forfeited. As a result, the Company did not recognize expense related to the SynBio Partner Warrants during the years ended December 31, 2019 and 2018.

On December 31, 2014, the Company granted Serum Institute a warrant to purchase 8,081 new shares of Common Stock at an exercise price of $95.04 per share, as adjusted ("Serum Institute 2014 Warrant"). The Serum Institute 2014 Warrant was exercisable in two equal tranches, each with separate non-market, performance-based vesting criteria. The Company used its judgment to assess the probability and timing of Serum Institute achieving these vesting criteria. These judgments were reassessed at each reporting period until the measurement date was reached. These warrants expired as of December 31, 2019.

In connection with the Serum Institute 2014 Warrant grant, warrants to purchase 410 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. These warrants expired as of December 31, 2019.

In 2016, the Company issued 17,677 warrants to purchase shares of Common Stock to Serum Institute with an exercise price of $95.04. The new warrants were fully vested and expensed at the time of grant.

The Company recognized warrant expense of approximately $10,000 during the year ended December 31, 2018 related to the Serum Institute 2014 Warrant and Serum Institute Partner Warrants. The Company did not recognize warrant expense during the year ended December 31, 2019. No collaboration or consulting service warrants were exercised or granted during the years ended December 31, 2019 and 2018. These outstanding warrants have an average weighted exercise price of $136.45 and expiration dates ranging from May 2020 through May 2021.

Warrants Related to Financing Arrangements

On July 17, 2019, in connection with the Offering, the Company offered to the purchasers Prefunded Warrants to purchase 570,000 shares of Common Stock. The Prefunded Warrants were exercisable beginning on July 17, 2019 at an exercise price of $0.01 per share. The Prefunded Warrants were sold at a price of $6.49 per Prefunded Warrant, which represented the per share purchase price for the shares less the $0.01 per share exercise price for each such Prefunded Warrant. The holders of the Prefunded Warrants did not have the right to exercise any portion of the Prefunded Warrant if the holder (together with its affiliates) would beneficially own in excess of 4.99% of the number of shares of our Common Stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Prefunded Warrants. All of the Prefunded Warrants to purchase 570,000 shares were exercised during the year ended December 31, 2019 resulting in net proceeds to the Company of $5,700. Also in connection with the Offering, the Company issued to the purchasers the Purchase Warrants. These Purchase Warrants have an exercise price of $13.00 per share, were exercisable beginning on July 17, 2019 and expire five years from such date. The warrants began trading on NASDAQ on July 23, 2019 under the symbol "XBIOW." The Purchase Warrants also provide that if the weighted-average price of Common Stock on any trading day on or after 30 days after issuance is lower than the then-applicable exercise price per share, each Purchase Warrant may be exercised, at the option of the holder, on a cashless basis for one share of Common Stock. Purchase Warrants to purchase approximately 2.2 million shares of Common Stock were exercised on a cashless, one-for-one basis during the year ended December 31, 2019. As of December 31, 2019, there were approximately 258,000 Purchase Warrants outstanding. Subsequent to December 31, 2019, Purchase Warrants to purchase an additional 219,000 shares of Common Stock were exercised on a cashless one-for-one basis.

On June 24, 2019, the Company entered into a consent agreement with certain holders of warrants to purchase shares of the Company's Common Stock whose consent was required to effect the Reverse Stock Split. In consideration of the holders' consent, the Company agreed to issue the holders warrants (the "Consent Warrants") to purchase 8,335 shares of the Company's Common Stock, at an exercise price per share based on a volume weighted average price for the five trading days following the effectiveness of the Reverse Stock Split. The Consent Warrants were issued on July 3, 2019 at an exercise price of $10.63. The Company evaluated the terms of the Consent Warrants and determined that they should be classified as equity instruments. The grant date fair value of these warrants was estimated to be $7.62 per share, for a total of approximately $64,000. The fair value of the Consent Warrants was estimated using a Black-Scholes model utilizing the following key valuation assumptions: the Company's stock price, a risk free rate of 1.83%, an expected life of 7 years and an expected volatility of 114.53%. The Company recorded approximately $64,000 as general and administrative expense during the year ended December 31, 2019. The Consent Warrants were subsequently modified to reflect an exercise price of $2.91 price per share in connection with the Offering. As a result of this modification, the Company recognized a $2,000 expense that was netted against the proceeds of the Offering.

In March 2019, in connection with its registered direct offering, the Company offered to the purchasers prefunded warrants to purchase 42,417 shares of Common Stock. The prefunded warrants were exercisable beginning on March 7, 2019 at an exercise price of $0.012 per share. The prefunded warrants were sold at a price of $23.988 per prefunded warrant, which represents the per share purchase price for the shares less the $0.012 per share exercise price for each such prefunded warrant. The holders of the prefunded warrants did not have the right to exercise any portion of the prefunded warrant if the holder (together with its affiliates) would beneficially own in excess of 9.99% of the number of shares of our Common Stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the prefunded warrants. All of these prefunded warrants were exercised during the year ended December 31, 2019 resulting in net proceeds to the Company of $509. In a concurrent private placement, the Company issued to the purchasers a warrant to purchase one share of the Company's Common Stock for each share and prefunded warrant (129,084 shares) purchased in the offering. These warrants have an exercise price of $27.00 per share, are exercisable beginning on September 8, 2019 and expire seven years from such date. As of December 31, 2019, all of these warrants were outstanding.

In addition to the prefunded and purchase warrants issued in the March 2019 registered direct offering and the Offering, the Company has outstanding debt and equity financing warrants to purchase an aggregate of 262,690 shares of Common Stock in connection with debt and equity financing arrangements as of December 31, 2019 and 2018 at a weighted average exercise price of $51.97 and expiration dates ranging from July 2020 through November 2021. Except for the March 2019 registered direct offering and the Offering, there were no debt and equity financing warrants granted or exercised during the year ended December 31, 2019. During the year ended December 31, 2018, debt and equity financing warrants to purchase approximately 31,000 shares of Common Stock were exercised resulting in approximately $1.5 million of net proceeds to the Company.

11. Share-Based Expense

Total share-based expense related to stock options, RSUs, Common Stock awards, and non-financing warrants was approximately $0.9 million and $1.4 million for the years ended December 31, 2019 and 2018, respectively. See Note 10, *Stockholders' Equity* for a discussion of the non-financing warrants.

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

	Year Ended December 31,	
	2019	**2018**
Research and development expenses	$ 126,933	$ 203,030
General and administrative expenses	726,584	1,228,757
	$ 853,517	$ 1,431,787

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 stock options issued in 2019 and 2018 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 and non-employee stock options. For all other 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 and non-employees. The expected life of non-employee options is the contractual life of the option. The expected volatility rates are estimated based on the actual volatility of the Company. To the extent Company data is not available for the full expected term of the awards the Company uses a price volatility based on a blended rate of the Company's 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. The Company accounts for forfeitures as they occur.

Employee Stock Options

During the years ended December 31, 2019 and 2018, 525,000 and 8,336 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 $1.24 and $31.51, respectively. No stock options were exercised during the years ended December 31, 2019 and 2018.

During the years ended December 31, 2019 and 2018, 27,831 and 43,712 total stock options vested, with total fair values of approximately $1.0 million and $1.6 million, respectively. As of December 31, 2019, there was approximately $0.7 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 2.4 years.

Key assumptions used in the Black-Scholes option pricing model for options granted to employees during the years ending December 31, 2019 and 2018 are as follows:

	Year Ended December 31,	
	2019	**2018**
Weighted-average expected dividend yield (%)	–	–
Weighted-average expected volatility (%)	156.78	118.03
Weighted-average risk-free interest rate (%)	1.71	2.90
Weighted-average expected life of option (years)	5.88	5.90
Weighted-average exercise price ($)	1.31	36.60

The following is a summary of employee stock option activity for the years ended December 31, 2019 and 2018:

	Number of shares	Weighted-average exercise price	Weighted-average remaining life (years)	Aggregate intrinsic value
Outstanding as of January 1, 2018	148,381	$ 47.90	8.53	$ 5,273
Granted	8,336	36.60		
Expired	(9,245)	68.76		
Outstanding as of December 31, 2018	147,472	45.95	8.17	$ –
Granted	525,000	1.31		
Expired	(10,413)	25.32		
Outstanding as of December 31, 2019	662,059	$ 10.88	9.34	$ 66,125
Vested or expected to vest as of December 31, 2019	662,059	$ 10.88	9.34	$ 66,125
Exercisable as of December 31, 2018	96,031	$ 49.34	7.92	$ –
Exercisable as of December 31, 2019	123,864	$ 47.69	7.10	$ –

A summary of the status of the Company's non-vested employee stock option shares as of December 31, 2019, and the changes during the year ended December 31, 2019, is as follows:

	Number of shares	Weighted-average grant date fair value
Balance as of January 1, 2019	51,439	$ 31.92
Granted	525,000	$ 1.24
Forfeited	(10,413)	$ 14.44
Vested	(27,831)	$ 37.37
Balance as of December 31, 2019	538,195	$ 2.05

Restricted Stock Units

There are 4,167 RSUs outstanding as of December 31, 2019 and 2018, respectively. There were no RSU grants for the years ended December 31, 2019 and 2018. The RSUs vest annually over a 3-year period and had a grant date fair value of $25.32. During the years ended December 31, 2019 and 2018, 1,389 RSUs were vested in each year and none expired, respectively.

Non-Employee Stock Options

Share-based 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. Prior to the adoption of ASU 2018-07, compensation expense related to stock options granted to non-employees was subject to re-measurement at each reporting period until the options vested. Commencing January 1, 2019, compensation expense related to stock options to non-employees is no longer subject to re-measurement.

During the years ended December 31, 2019 and 2018, 15,500 and 834 total stock options to purchase shares of Common Stock were granted by the Company to non-employees, respectively.

During the year ended December 31, 2018, 834 total stock options vested, with total fair values of approximately $36,000. No non-employee stock options vested during the year ended December 31, 2019. For the years ended December 31, 2019 and 2018, the Company recognized approximately $3,000 and $36,000, 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, 2019 and 2018:

	Number of shares	Weighted-average exercise price	Weighted-average remaining life (years)	Aggregate intrinsic value
Outstanding as of January 1, 2018	4,731	$ 90.49	6.31	$ –
Granted	834	23.16		
Expired	(263)	219.00		
Outstanding as of December 31, 2018	5,302	73.52	5.40	$ –
Granted	15,500	1.08		
Expired	(242)	225.72		
Outstanding as of December 31, 2019	20,560	$ 17.09	4.74	$ –
Vested or expected to vest as of December 31, 2019	20,560	$ 17.09	4.74	$ –
Exercisable as of December 31, 2018	5,302	$ 73.52	5.40	$ –
Exercisable as of December 31, 2019	5,060	$ 66.15	4.63	$ –

A summary of the status of the Company's non-vested non-employee stock option shares as of December 31, 2019, and the changes during the year ended December 31, 2019 is as follows:

	Number of shares	Weighted-average grant date fair value
Balance as of January 1, 2019	–	$ –
Granted	15,500	$ 0.94
Vested	–	$ –
Balance as of December 31, 2019	15,500	$ 0.94

Common Stock Awards

The Company granted 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 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, 2019 and 2018 are as follows:

	Number of shares
Balance as of January 1, 2018	5,237
Granted	2,167
Issued	–
Balance as of December 31, 2018	7,404
Granted	9,026
Issued	(7,836)
Balance as of December 31, 2019	8,594

The Company granted 9,026 and 2,167 shares of Common Stock during the years ended December 31, 2019 and 2018, respectively, in exchange for professional services. As all services were rendered in each respective period, expense related to Common Stock awards of approximately $47,000 and $70,000 was recognized during the years ended December 31, 2019 and 2018, respectively. The balance of the Common Stock awards has not been issued as of December 31, 2019.

Joint Share Ownership Plan

As of December 31, 2019 and 2018, there were approximately 27,000 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, 2019 and 2018, respectively.

12. 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. There were no company contributions to the 401(k) Plan during the years ended December 31, 2019 and 2018, respectively.

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. There were no contributions for the years ended December 31, 2019 and 2018, respectively.

13. Commitments and Contingent Liabilities

Leases

The Company determines whether an arrangement is a lease at inception. In January 2019, the Company entered into a sublease and relocated its corporate headquarters from Lexington, Massachusetts to Framingham, Massachusetts. This sublease called for total future minimum rent payments of approximately $52,000 at inception and has a termination date of September 30, 2020, which corresponds to the underlying base lease. The Company does not have options to extend, termination options or material residual value guarantees. The Company recorded a right-of-use ("ROU") asset and corresponding lease liability on the consolidated balance sheet. The Company recognized a ROU asset and a lease liability of approximately $43,000 during the year ended December 31, 2019. As the sublease does not provide an implicit rate, we used our incremental borrowing rate (10.2%) based on the information available at the lease's commencement date in determining the present value of lease payments.

Supplemental cash flow information and non-cash activity related to our operating leases are as follows:

	Year Ended December 31, 2019
Operating cash flow information:	
Cash paid for amounts included in the measurement of lease liabilities	$ 23,288
Non-cash activity:	
Right-of-use assets obtained in exchange for lease obligations	$ 43,330

Supplemental balance sheet information related to our operating leases is as follows:

	Balance Sheet Classification	December 31, 2019
Right-of-use assets	Prepaid expenses and other	$ 20,042
Current lease liabilities	Accrued expenses and other current liabilities	$ 20,042
Non-current lease liabilities	Other liabilities	$ –

The Company did not apply the provisions of ASU 2016-02 to the lease of its former headquarters in Lexington, Massachusetts or its office space lease in Miami, Florida as they did not have a material impact on the Company's consolidated financial statements or the Company's accumulated deficit as of the beginning of 2019. The lease of the Company's former headquarters expired on January 31, 2019 and the Miami office space lease expired in November 2019. During the fourth quarter of 2019, the Company renewed its Miami office lease for twelve-months to November 2020. As this lease has a term of 12-months at inception, the Company will account for it as an operating lease. As of December 31, 2019, total minimum lease payments on this lease was approximately $19,000.

14. Related Party Transactions

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

During the third quarter of 2019, the Company entered into a sponsored research agreement with Pharmsynthez related to experiments identified by the Company to support its efforts as it prepares for initial tech transfer of the XCART methods to a future academic collaborator. Under the agreement, the Company made a $350,000 payment to Pharmsynthez during the third quarter of 2019, which is refundable on pro rata basis if the project is terminated prematurely as a result of Pharmsynthez failing to perform the work. The Company expensed approximately $155,000 related to this agreement during the year ended December 31, 2019. As of December 31, 2019, approximately $195,000 was recorded as an advanced payment and included in Prepaid expenses and other on the December 31, 2019 consolidated balance sheet.

On July 19, 2019, the Company acquired the XCART technology platform from Hesperix and OPKO. Dr. Genkin is a director and significant shareholder of Hesperix. In addition, the Company agreed to repay an approximate $225,000 loan that Dr. Genkin entered into with Hesperix. Mr. Adam Logal, one of our directors, is Senior Vice President, Chief Financial Officer, Chief Accounting Officer and Treasurer of OPKO Health, Inc., the parent company of OPKO.

In October 2019, the Company entered into the Pharmsynthez Loan pursuant to which the Company advanced Pharmsynthez an aggregate principal amount of up to $500,000 to be used for the development of a specific product under the Co-Development Agreement. The Pharmsynthez Loan has a term of 15-months and accrues interest at a rate of 10% per annum. The Pharmsynthez Loan is guaranteed by all of the operating subsidiaries of Pharmsynthez, including SynBio and AS Kevelt, and is secured by all of the equity interests of the Company owned by Pharmsynthez and SynBio. The Company recognized approximately $9,000 of interest income related to this loan during the twelve-months ended December 31, 2019.

Please refer to Note 3, *Significant Strategic Drug Development Collaborations – Related Parties,* and Note 10, *Stockholder's Equity*, for details on arrangements with collaboration partners that are also related parties.

15. 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, other than as disclosed in *Note 10, Stockholder's Eq*uity, there were no such events requiring recognition or disclosure in the financial statements.

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, 2019, 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 quarterly 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 2020 Annual Meeting of Stockholders within 120 days of the end of the Company's fiscal year ended December 31, 2019 and is incorporated herein by reference, or will be included in an amendment to this Annual Report on Form 10-K.

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 2020 Annual Meeting of Stockholders within 120 days of the end of the Company's fiscal year ended December 31, 2019 and is incorporated herein by reference, or will be included in an amendment to this Annual Report on Form 10-K.

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 2020 Annual Meeting of Stockholders within 120 days of the end of the Company's fiscal year ended December 31, 2019 and is incorporated herein by reference, or will be included in an amendment to this Annual Report on Form 10-K.

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 2020 Annual Meeting of Stockholders within 120 days of the end of the Company's fiscal year ended December 31, 2019 and is incorporated herein by reference, or will be included in an amendment to this Annual Report on Form 10-K.

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 2020 Annual Meeting of Stockholders within 120 days of the end of the Company's fiscal year ended December 31, 2019 and is incorporated herein by reference, or will be included in an amendment to this Annual Report on Form 10-K.

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:* All 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 76 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	Order of the High Court of Justice, Chancery Division, entered January 23, 2014	8-K	01/29/2014	2.1	
2.2	Share Purchase Agreement between Xenetic Biosciences, Inc., Hesperix SA, certain Sellers and Alexey Andreevich Vinogradov, dated March 1, 2019	8-K/A	05/13/2019	2.1	
2.3	First Amendment to Share Purchase Agreement dated June 7, 2019	8-K	06/13/2019	2.1	
2.4	Second Amendment to Share Purchase Agreement dated June 24, 2019	8-K	06/24/2019	2.1	
2.5	Third Amendment to Share Purchase Agreement dated July 15, 2019	8-K	07/16/2019	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	
3.10	Certificate of Change Pursuant to NRS 78.209	8-K	06/24/2019	3.1	
3.11	Certificate of Amendment to Articles of Incorporation	8-K	06/24/2019	3.2	
4.1	Description of Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934				X
4.2	Form of Common Stock Certificate of the Registrant	S-1/A	07/14/2016	4.1	
4.3	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	
4.4	SynBio LLC Warrant to Purchase Common Stock of Xenetic Bioscience, Inc.	10-K	04/15/2015	10.2	
4.5	Serum Institute of India Limited Warrant to Purchase Common Stock of Xenetic Bioscience, Inc.	10-K	04/15/2015	10.03	
4.6	Firdaus Jal Dastoor Warrant to Purchase Common Stock of Xenetic Bioscience, Inc.	10-K	04/15/2015	10.04	
4.7	Form of Common Stock Purchase Warrant	8-K	11/16/2015	10.3	
4.8	Form of Management Common Stock Purchase Warrant	8-K	11/16/2015	10.4	
4.9	Form of Amended and Restated Common Stock Purchase Warrant	8-K	11/16/2015	10.6	
4.10	Form of Common Stock Purchase Warrant	8-K	07/08/2016	10.3	
4.11	Form of Common Stock Purchase Warrant	S-1/A	10/31/2016	10.53	
4.12	Form of Ten Percent (10%) Senior Secured Convertible Promissory Note	8-K	11/16/2015	10.2	
4.13	Form of Ten Percent (10%) Junior Secured Convertible Promissory Note – Due Deferral End Date	8-K	07/08/2016	10.2	

Exhibit No.	Exhibit Index	Form	Filing Date	Exhibit Number	Filed Herewith
4.14	Form of Amended and Restated Ten Percent (10%) Senior Secured Convertible Promissory Note	8-K	11/16/2015	10.5	
4.15	Registration Rights Agreement, dated July 1, 2015, between Xenetic Bioscience, Inc. and OJSC Pharmsynthez	8-K	07/08/2015	10.3	
4.16	Form of First Amendment to Registration Rights Agreement	8-K	11/16/2015	10.8	
4.17	Form of Pre-Funded Common Stock Purchase Warrant	8-K	03/07/2019	4.1	
4.18	Form of Common Stock Purchase Warrant	8-K	03/07/2019	4.2	
4.19	Form of Common Stock Purchase Warrant	8-K	06/25/2019	4.1	
4.20	Form of Pre-Funded Common Stock Purchase Warrant	8-K	07/22/2019	4.1	
4.21	Form of Common Stock Purchase Warrant	8-K	07/22/2019	4.2	
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	
10.7†	Form of Amended and Restated Xenetic Biosciences, Inc. Equity Incentive Plan, effective as of December 4, 2019	DEF14A	11/08/2019	Appendix A	
10.8	Stock Purchase Agreement, dated January 29, 2014, between Xenetic Biosciences, Inc. and Baxter Healthcare SA	10-K/A	02/18/2015	10.08	
10.9	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	
10.10#	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	
10.11#	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	
10.12#	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	

Exhibit No.	Exhibit Index	Form	Filing Date	Exhibit Number	Filed Herewith
10.13#	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	
10.14#	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	
10.15#	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	
10.16#	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	
10.17#	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	
10.18#	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	
10.19#	Collaboration, License and Development Agreement, dated November 11, 2009, between Pharmsynthez ZAO and Lipoxen Technologies Ltd.	10-K/A	02/18/2015	10.20	
10.20#	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	
10.21	Intellectual Property Assignment between Dmitry Genkin, FDS Pharma, Lipoxen Technologies Limited and Xenetic Biosciences Inc.	10-K	04/15/2015	10.1	
10.22	Securities Purchase Agreement, dated May 2015, between Xenetic Bioscience, Inc. and OJSC Pharmsynthez	8-K	07/08/2015	10.1	
10.23	Security Agreement dated July 1, 2015, between Xenetic Bioscience, Inc. and OJSC Pharmsynthez	8-K	07/08/2015	10.4	
10.24	Subsidiary Guarantee dated July 1, 2015, between Xenetic Bioscience, Inc. and OJSC Pharmsynthez	8-K	07/08/2015	10.5	
10.25	Form of Assignment and Assumption Agreement	8-K	07/08/2015	10.7	
10.26#	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	
10.27	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	
10.28	Form of First Amendment to Securities Purchase Agreement	8-K	11/16/2015	10.7	
10.29	Form of First Amendment to Security Agreement	8-K	11/16/2015	10.9	
10.30	Form of First Amendment to Subsidiary Guarantee	8-K	11/16/2015	10.10	
10.31	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	

Exhibit No.	Exhibit Index	Form	Filing Date	Exhibit Number	Filed Herewith
10.32†	Employment Agreement, dated December 1, 2016, between Xenetic Biosciences, Inc. and Jeffrey Eisenberg	8-K	12/6/2016	10.1	
10.33†	Employment Agreement, dated January 1, 2017 between Xenetic Biosciences, Inc. and Curtis Lockshin	8-K	01/04/2017	10.1	
10.34†	Employment Agreement, dated March 23, 2017 between Xenetic Biosciences, Inc. and James F. Parslow	8-K	04/04/2017	10.1	
10.35†	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	
10.36†	Amended and Restated Employment Agreement, dated October 26, 2017, between Xenetic Biosciences, Inc. and Jeffrey Eisenberg	10-K	03/30/2018	10.45	
10.37#	Right to Sublicense Agreement, dated October 27, 2017, by and among Xenetic Biosciences, Inc., Baxalta Incorporated, Baxalta US Inc., and Baxalta GmbH	10-K	03/30/2018	10.46	
10.38†	Settlement Agreement, dated November 3, 2017, by and among M. Scott Maguire, Xenetic Biosciences (UK) Limited and Lipoxen Technologies, Limited	10-K	03/30/2018	10.47	
10.39	Assignment Agreement between Xenetic Biosciences, Inc. and OPKO Pharmaceuticals, LLC, dated March 1, 2019	8-K/A	05/20/2019	10.1	
10.40	First Amendment to Assignment Agreement dated June 7, 2019	8-K	06/13/2019	10.1	
10.41	Second Amendment to Assignment Agreement dated June 24, 2019	8-K	06/24/2019	10.1	
10.42	Third Amendment to Assignment Agreement dated July 15, 2019	8-K	07/16/2019	10.1	
10.43	Voting Agreement between Xenetic Biosciences, Inc. and PJSC Pharmsynthez, dated March 1, 2019	8-K	03/04/2019	10.1	
10.44	Voting Agreement between Xenetic Biosciences, Inc. and OPKO Pharmaceuticals, LLC, dated March 1, 2019	8-K	03/04/2019	10.2	
10.45	Voting Agreement between Xenetic Biosciences, Inc. and Dr. Dmitry Dmitrievich Genkin, dated March 1, 2019	8-K	03/04/2019	10.3	
10.46	Form of Securities Purchase Agreement entered into as of March 5, 2019, by and among Xenetic Biosciences, Inc. and those purchase parties thereto.	8-K	03/07/2019	10.1	
10.47	Form of Consent Agreement by and among Xenetic Biosciences, Inc. and certain purchasers dated June 24, 2019	8-K	06/25/2019	10.1	
10.48	Warrant Agency Agreement, between Xenetic Biosciences, Inc. and Empire Stock Transfer, Inc. dated July 19, 2019	8-K	07/22/2019	10.1	
10.49	Consent Agreement by and among Xenetic Biosciences, Inc. and certain purchasers dated July 16, 2019	8-K	07/16/2019	10.1	
10.50†	Letter Agreement re. Appointment of Non – Employee, Independent Director of Xenetic Biosciences, Inc. for Grigory G. Borisenko, effective as of September 26, 2019				X
10.51†	Form of Letter Agreement re. Appointment of Non – Employee, Independent Director of Xenetic Biosciences, Inc.				X
10.52†	Form of Xenetic Biosciences, Inc. Stock Option Grant Notice				X
10.53†	Xenetic Biosciences, Inc. Stock Option Grant Notice, dated December 4, 2019, between Jeffrey Eisenberg and Xenetic Biosciences, Inc.				X

Exhibit No.	Exhibit Index	Form	Filing Date	Exhibit Number	Filed Herewith
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 26, 2020 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 26th day of March, 2020.

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/ GRIGORY BORISENKO Grigory Borisenko	Director
/s/ JAMES CALLAWAY James Callaway	Director
/s/ FIRDAUS JAL DASTOOR, FCS Firdaus Jal Dastoor, FCS	Director
/s/ DMITRY GENKIN Dmitry Genkin	Director
/s/ ROGER KORNBERG Roger Kornberg	Director
/s/ ADAM LOGAL Adam Logal	Director
/s/ ALEXEY VINOGRADOV Alexey Vinogradov	Director

Exhibit 4.1

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

When used herein, the terms the "Company", "we," "our," and "us" refer to Xenetic Biosciences, Inc.

The following summary describes our capital stock and the material provisions of our articles of incorporation, as amended, and our amended and restated bylaws. Because the following is only a summary, it does not contain all of the information that may be important to you. For a complete description, you should refer to our articles of incorporation, as amended, and our amended and restated bylaws, copies of which are incorporated by reference as exhibits to our Annual Report on Form 10-K for the year ended December 31, 2019 of which this Exhibit 4.1 is a part.

DESCRIPTION OF CAPITAL STOCK

Our charter provides that we may issue up to 12,500,000 shares of Common Stock, $0.001 par value per share (the "Common Stock"), and 10,000,000 shares of preferred stock, $0.001 par value per share, 1,000,000 of which are designated as Series A Preferred Stock, 2,500,000 of which are designated as Series B Preferred Stock, and 6,500,000 of which shares of preferred stock are undesignated. As of December 31, 2019, there were outstanding: 6,065,441 shares of Common Stock, 970,000 shares of Series A Preferred Stock, 1,804,394 shares of Series B Preferred Stock. Under Nevada law, stockholders are not generally liable for our debts or obligations.

DESCRIPTION OF COMMON STOCK

Voting Rights

Common Stock is entitled to one vote per share on all matters submitted to a vote of the stockholders, including the election of directors. Except as otherwise required by law or provided in any resolution adopted by our board of directors with respect to any series of preferred stock, the holders of our Common Stock will possess all voting power. Generally, all matters to be voted on by stockholders must be approved by a majority (or, in the case of election of directors, by a plurality) of the votes entitled to be cast by all shares of our Common Stock that are present in person or represented by proxy, subject to any voting rights granted to holders of any preferred stock. Our stockholders do not have cumulative voting rights in the election of directors. Holders of our Common Stock representing 50% of our capital stock issued, outstanding and entitled to vote, represented in person or by proxy, are necessary to constitute a quorum at any meeting of our stockholders. A vote by the holders of a majority of our outstanding shares is required to effectuate certain fundamental corporate changes such as liquidation, merger or an amendment to our charter.

Dividends

Subject to the preferential rights of any other class or series of shares of stock created from time to time by our board of directors from time to time, the holders of shares of our Common Stock will be entitled to such cash dividends, non-cumulative, as may be declared from time to time by our board of directors from funds available therefore. We will not pay any dividends on shares of Common Stock (other than dividends in the form of Common Stock) unless and until such time as we pay dividends on our preferred stock on an as-converted basis.

Liquidation

Subject to the preferential rights of any other class or series of shares of stock created from time to time by our board of directors, upon liquidation, dissolution or winding up, the holders of shares of our Common Stock will be entitled to share ratably in the assets of the Company available for distribution to such holders.

Rights and Preferences

In the event of any merger or consolidation with or into another company in connection with which shares of our Common Stock are converted into or exchangeable for shares of stock, other securities or property (including cash), all holders of our Common Stock will be entitled to receive the same kind and amount of shares of stock and other securities and property (including cash). Holders of our Common Stock have no pre-emptive, conversion, subscription or other rights and there are no redemption or sinking fund provisions applicable to our Common Stock. The rights, preferences and privileges of the holders of our Common Stock are subject to and may be adversely affected by the rights of the holders of shares of any series of our preferred stock that we may designate in the future.

Fully Paid and Nonassessable

All of our outstanding shares of Common Stock are duly authorized, validly issued, fully paid and nonassessable.

Exchange Listing

Our Common Stock is traded on the NASDAQ Capital Market under the trading symbol "XBIO."

DESCRIPTION OF PURCHASE WARRANTS

The following summary of certain terms and provisions ofwarrants to purchase 2,300,000 shares of the Common Stock (the "Purchase Warrants")is not complete and is subject to, and qualified in its entirety by the provisions of, the Purchase Warrants. For a complete description, you should refer to the form of Purchase Warrant, a copy of which is incorporated by reference as an exhibit to our Annual Report on Form 10-K for the year ended December 31, 2019 of which this Exhibit 4.1 is a part.

Exercisability

The Purchase Warrants are exercisable beginning on the date of original issuance and at any time up to the date that is five years after their original issuance. The Purchase Warrants will be exercisable, at the option of each holder, in whole or in part by delivering to us a duly executed exercise notice and, at any time a registration statement registering the issuance of the shares of Common Stock underlying the Purchase Warrants under the Securities Act of 1933, as amended (the "Securities Act") is effective and available for the issuance of such shares, or an exemption from registration under the Securities Act is available for the issuance of such shares, by payment in full in immediately available funds for the number of shares of Common Stock purchased upon such exercise. If a registration statement registering the issuance of the shares of Common Stock underlying the Purchase Warrants under the Securities Act is not effective or available and an exemption from registration under the Securities Act is not available for the issuance of such shares, the holder may, in its sole discretion, elect to exercise the Purchase Warrant through a cashless exercise, in which case the holder would receive upon such exercise the net number of shares of Common Stock determined according to the formula set forth in the Purchase Warrant. In addition, the Purchase Warrant may be exercised on a cashless basis beginning 30 days from the pricing of the Purchase Warrant ("Cashless Date") if the VWAP (as defined in the Purchase Warrant) of the Common Stock on any Trading Day (as defined in the Purchase Warrant) on or after the Cashless Date fails to exceed the exercise price in effect on such date (as may be subject to adjustment). The number of shares of Common Stock issuable in such cashless exercise shall equal the number of shares of Common Stock that would be issuable upon exercise of the Purchase Warrant in accordance with it terms if such exercise were by means of a cash exercise. No fractional shares of Common Stock will be issued in connection with the exercise of a Purchase Warrant. In lieu of fractional shares, we will pay the holder an amount in cash equal to the fractional amount multiplied by the exercise price.

Exercise Limitation

A holder will not have the right to exercise any portion of the Purchase Warrant if the holder (together with its affiliates) would beneficially own in excess of 4.99% (or, upon election of the holder, 9.99%) of the number of shares of our Common Stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Purchase Warrants. However, any holder may increase or decrease such percentage, provided that any increase will not be effective until the 61st day after such election.

Exercise Price

The Purchase Warrants will have an exercise price of $13.00 per share. The exercise price is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our Common Stock and also upon any distributions of assets, including cash, stock or other property to our stockholders.

Transferability

Subject to applicable laws, the Purchase Warrants may be offered for sale, sold, transferred or assigned without our consent.

Exchange Listing

The Purchase Warrants are traded on the NASDAQ Capital Market under the symbol "XBIOW."

Fundamental Transactions

If a fundamental transaction occurs, then the successor entity will succeed to, and be substituted for us, and may exercise every right and power that we may exercise and will assume all of our obligations under the Purchase Warrants with the same effect as if such successor entity had been named in the Purchase Warrant itself. If holders of our Common Stock are given a choice as to the securities, cash or property to be received in a fundamental transaction, then the holder shall be given the same choice as to the consideration it receives upon any exercise of the Purchase Warrant following such fundamental transaction.

Rights as a Stockholder

Except as otherwise provided in the Purchase Warrants or by virtue of such holder's ownership of shares of our Common Stock, the holder of a Purchase Warrant does not have the rights or privileges of a holder of our Common Stock, including any voting rights, until the holder exercises the Purchase Warrant.

ANTI-TAKEOVER EFFECTS

Certain provisions of the Company's articles of incorporation, as amended, the Company's amended and restated bylaws, and the Nevada Revised Statutes (the "NRS") may be deemed to have an anti-takeover effect. Such provisions may delay, deter or prevent a tender offer or takeover attempt that a stockholder might consider to be in that stockholder's best interests, including attempts that might result in a premium over the market price for the shares held by stockholders.

The NRS permits, if authorized by the Company's articles of incorporation, as amended, the issuance of blank check preferred stock with preferences, limitations and relative rights determined by a corporation's board of directors without stockholder approval.

The Company's articles of incorporation, as amended, currently authorizes the issuance of blank check preferred stock, of which 6,500,000 preferred shares are available for future issuance in one or more series to be issued from time to time.

The Company has opted out of NRS 78.411 to 78.444, which prohibits Nevada corporations from engaging in any "combination" with an "interested stockholder" for a period of two years following the date that the stockholder became an "interested stockholder" unless prior to that time the Board of Directors of the corporation approved either the "combination" or the transaction which resulted in the stockholder becoming an "interested stockholder."

Each of the foregoing may have the effect of preventing or rendering more difficult or costly, the completion of a takeover transaction that stockholders might view as being in their best interests.

Exhibit 10.50

Xenetic Biosciences, Inc.
40 Speen Street,
Suite 102
Framingham, MA 01701
t 781-778-7720
e info@xeneticbio.com

Effective as of September 26, 2019

Mr. Grigory G. Borisenko

6-20 Pobedy Street

Apartment 7

Moscow Region

Town of Khimki, Russia

Re: Board of Directors Appointment
Dear Mr. Borisenko:

This Letter Agreement (the "Agreement") is to confirm the terms of your proposed appointment on September 26, 2019 as a non-employee, independent Director of the Board of Directors (the "Board") of Xenetic Biosciences, Inc. (the "Company").

Overall, in terms of time commitment, we expect your attendance at all the meetings of the Board 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 The 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 the Company's business, provided that such expenses are against original and valid receipts (the "Expenses").

    1.2 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 Agreement.

    1.3 For the avoidance of any doubt, 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. You hereby acknowledge and agree that pursuant to the Company's director compensation policy, you are entitled to receive certain other compensation for your service as a member of the Board, including cash retainers and stock options to purchase shares of the Company's common stock, and that you hereby waive such rights to compensation that would otherwise be due to you.

2. The term of your appointment as a non-employee, independent director of the Company shall be for one year or until the next Annual Meeting of Shareholders 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, ensuring that the necessary financial and human resources are in place for the Group to meet its objectives and reviewing management performance; and

   4.3 Setting the Group's values and standards and ensuring that its obligations to its shareholders and others are understood and met, including, but not limited to:

      A. Managing conflicts of interest that may arise in Board meetings; and

      B. 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 fulfill 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 Section 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.

6. Blackout Period. You understand that we have, or intend to have, a policy pursuant to which, among other restrictions, no officer, director or key executive (or any of their affiliates) may engage in transactions in our stock during the periods commencing at the close of business on the 15th day before the end of each fiscal quarter and ending after markets close on the second full trading day after the financial information for the then-current quarter has been publicly released, subject to the terms and conditions of the Company's policy.

7. Term and Termination.

7.1 Subject to Section 7.2 hereunder, this Agreement and appointment shall terminate immediately and without claim for compensation on the occurrence of any of the following events:

A. If you resign as a Director of the Company for any reason; and/or

B. If you are removed or not re-appointed as a Director of the Board at an Annual 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 and/or the Company's Articles of Incorporation; and/or

C. If you have been declared bankrupt or made an arrangement or composition with or for the benefit of your creditors; and/or

D. 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

E. If an order of a court having jurisdiction over the Company requires you to resign.

7.2 Any termination of this Agreement shall be without payment of damages or compensation (except that you shall be entitled to any accrued Expenses properly incurred under the terms of this Agreement prior to the date of such termination).

8. 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.

9. 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.

10. Subject to the proper performance of your obligations to the Company under this Agreement and any applicable law, the Company agrees that you will be free to accept other appointments, directorships and chairmanships provided that:

    10.1 They do not in any way conflict with the interests of the Company or any member of the Group; and

    10.2 They do not restrict you from devoting the necessary time and attention properly to services to be performed under this Agreement; and

    10.3 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.

11. 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.

12. 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.

13. This Agreement refers to your appointment as a Director of the Company and your future membership on the committees of the Board.

14. You shall ensure that you comply at all times with the Company's inside trading policies as in effect from time to time.

15. You shall discharge your general duties as a Director pursuant to the Company's Articles of Incorporation, Bylaws and applicable law.

16. This Agreement shall be governed by and construed in accordance with the law of the State of Massachusetts.

Please sign the attached copy of this Agreement and return it to the Company to signify your acceptance of the terms set out above.

**

Sincerely yours,

XENETIC BIOSCIENCES INC.

/s/ Jeffrey Eisenberg
Name: Jeffrey Eisenberg
Title Chief Executive Officer

AGREED AND ACKNOWLEDGED BY:

/s/ Grigory G. Borisenko
Name of Director: Grigory G. Borisenko

Exhibit 10.51

Xenetic Biosciences, Inc.
40 Speen Street,
Suite 102
Framingham, MA 01701
t 781-778-7720
e info@xeneticbio.com

[DATE]
[NAME]
[ADDRESS]

Re: Board of Directors Appointment

Dear [_____]:

This Letter Agreement (the "Agreement") is to confirm the terms of your proposed appointment on [_____] as a non-employee, [independent] Director of the Board of Directors (the "Board") of Xenetic Biosciences, Inc. (the "Company").

Overall, in terms of time commitment, we expect your attendance at all the meetings of the Board 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 $[_____] 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 Option. 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 from time to time (the "Plan") and upon such terms and conditions as determined by the Compensation Committee or the Board (as applicable), an option to purchase [_____] shares of common stock of the Company at a strike price determined by the closing price of the common stock on the date of such grant (the "Initial Option"). 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. An additional option to purchase [____] 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 [____] Annual Meeting of Shareholders (together with the Initial Option, the "Options"). The exercise price shall be determined by the closing price of the common stock on the date of such grant.

If your service on the Board 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 following the termination of your Board position (the "Termination Exercise Period"). Any Options that are not exercised within the Termination Exercise Period shall expire immediately.

A. 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 Agreement, 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 Agreement.

B. Vesting. All Options granted to you shall vest as provided in Section 1.2.

C. Price. The exercise price of the Options shall be equal to the Company's closing stock price on the date of your grant.

D. 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 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 Agreement and the provisions of the Plan, the provisions of the Plan shall supersede.

E. Certain Representations. You represent and agree that you are accepting the option to purchase shares of the Company's 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 The 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 the Company's 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 Agreement.

1.5 For the avoidance of any doubt, the Board Meeting 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, [independent] director of the Company shall be for one year or until the next Annual Meeting of Shareholders 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, ensuring that the necessary financial and human resources are in place for the Group to meet its objectives and reviewing management performance; and

4.3 Setting the Group's values and standards and ensuring that its obligations to its shareholders and others are understood and met, including, but not limited to:

A. Managing conflicts of interest that may arise in Board meetings; and

B. 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 fulfill 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 Section 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.

6. Blackout Period. You understand that we have, or intend to have, a policy pursuant to which, among other restrictions, no officer, director or key executive (or any of their affilaites) may engage in transactions in our stock during the periods commencing at the close of business on the 15th day before the end of each fiscal quarter and ending after markets close on the second full trading day after the financial information for the then-current quarter has been publicly released, subject to the terms and conditions of the Company's policy.

7. Term and Termination.

7.1 Subject to Section 7.2 hereunder, this Agreement and appointment shall terminate immediately and without claim for compensation on the occurrence of any of the following events:

A. If you resign as a Director of the Company for any reason; and/or

B. If you are removed or not re-appointed as a Director of the Board at an Annual 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 and/or the Company's Articles of Incorporation; and/or

C. If you have been declared bankrupt or made an arrangement or composition with or for the benefit of your creditors; and/or

D. 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

E. If an order of a court having jurisdiction over the Company requires you to resign.

6.2 Any termination of this Agreement shall be without payment of damages or compensation (except that you shall be entitled to any accrued Board Meeting Fees or Expenses properly incurred under the terms of this Agreement 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 Agreement 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 Agreement; 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 Agreement refers to your appointment as a Director of the Company and your future 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, Bylaws and applicable law.

15. This Agreement shall be governed by and construed in accordance with the law of the State of Massachusetts.

Please sign the attached copy of this Agreement and return it to the Company to signify your acceptance of the terms set out above.

***

Sincerely yours,

XENETIC BIOSCIENCES INC.

_____
Name: Jeffrey Eisenberg
Title: Chief Executive Officer

AGREED AND ACKNOWLEDGED BY:

Name of Director:

Exhibit 10.52

Option No.

XENETIC BIOSCIENCES, INC.

Stock Option Grant Notice
Stock Option Grant under the
Amended and Restated Xenetic Biosciences, Inc.
Equity Incentive Plan, adopted by the Board of Directors on September 26, 2019 and approved by stockholders on December 4, 2019

1. Name and Address of Participant: _____
_____
_____

2. Date of Option Grant: _____

3. Type of Grant: _____
4. Maximum Number of Shares for which this Option is exercisable: _____

5. Exercise (purchase) price per share: _____

6. Option Expiration Date: _____
7. Vesting Start Date: _____
8. Vesting Schedule: This Option shall become exercisable (and the Shares issued upon exercise shall be vested) as follows provided the Participant is an Eligible Employee, director or Consultant of the Company or of an Affiliate on the applicable vesting date:

The foregoing rights are cumulative and are subject to the other terms and conditions of the Agreement and the Amended and Restated Xenetic Biosciences, Inc. Equity Incentive Plan adopted by the Board of Directors on September 26, 2019 and approved by stockholders on December 4, 2019, as amended from time to time (the "Plan").

Notwithstanding the foregoing or any terms in the Agreement or the Plan to the contrary, in the event of a Change in Control (as defined in the Plan) all of the Shares which would have vested in each vesting installment(s) remaining under this Option will be vested and exercisable upon the Change in Control.

Notwithstanding the foregoing, unless otherwise approved by the Administrator in its sole discretion, the Option shall only be exercised from and after the date the Company has filed a Form S-8 registration statement with the U.S. Securities and Exchange Commission covering the Shares authorized under the Plan.

The Company and the Participant acknowledge receipt of this Stock Option Grant Notice and agree to the terms of the Stock Option Agreement Incorporated Terms and Conditions (attached hereto and incorporated by reference herein (the "Agreement")), the Plan and the terms of this Option Grant as set forth above.

XENETIC BIOSCIENCES, INC.

By:_____
Name:
Title:

_____
Participant

XENETIC BIOSCIENCES, INC.

STOCK OPTION AGREEMENT - INCORPORATED TERMS AND CONDITIONS

AGREEMENT made as of the date of grant set forth in the Stock Option Grant Notice by and between Xenetic Biosciences, Inc. (the "Company"), a Nevada corporation, and the individual whose name appears on the Stock Option Grant Notice (the "Participant").

WHEREAS, the Company desires to grant to the Participant an Option to purchase shares of its common stock, $0.001 par value per share (the "Shares"), under and for the purposes set forth in the Amended and Restated Xenetic BioSciences, Inc. Equity Incentive Plan, adopted by the Board of Directors on September 26, 2019 and adopted by stockholders on December 4, 2019, as amended from time to time (the "Plan"), and any rules and regulations promulgated by the Committee with respect to the Plan;

WHEREAS, the Company and the Participant understand and agree that any terms used and not defined herein have the same meanings as in the Plan; and

WHEREAS, the Company and the Participant each intend that the Option granted herein shall be of the type set forth in the Stock Option Grant Notice.

NOW, THEREFORE, in consideration of the mutual covenants hereinafter set forth and for other good and valuable consideration, the parties hereto agree as follows:

1. GRANT OF OPTION.

The Company hereby grants to the Participant the right and option to purchase all or any part of an aggregate of the number of Shares set forth in the Stock Option Grant Notice, on the terms and conditions and subject to all the limitations set forth therein and herein (collectively, the "Agreement"), under United States securities and tax laws, and in the Plan, which is incorporated herein by reference. The Participant acknowledges receipt of a copy of the Plan.

2. EXERCISE PRICE.

The exercise price of the Shares covered by the Option shall be the amount per Share set forth in the Stock Option Grant Notice, subject to adjustment, as provided in the Plan, in the event of a stock split, reverse stock split or other events affecting the holders of Shares after the date hereof (the "Exercise Price"). Payment shall be made in accordance with Section 5(c) of the Plan.

3. EXERCISABILITY OF OPTION.

Subject to the terms and conditions set forth in this Agreement and the Plan, the Option granted hereby shall become vested and exercisable as set forth in the Stock Option Grant Notice and is subject to the other terms and conditions of this Agreement and the Plan.

4. TERM OF OPTION.

This Option shall terminate on the Option Expiration Date as specified in the Stock Option Grant Notice and, if this Option is designated in the Stock Option Grant Notice as an Incentive Stock Option (an "ISO") and the Participant is a 10% Stockholder, such date may not be more than five years from the date of this Agreement, but shall be subject to earlier termination as provided herein or in the Plan.

If the Participant ceases to be an Employee, director or Consultant of the Company or of an Affiliate for any reason other than the death or Disability of the Participant, or termination of the Participant for Cause (the "Termination Date"), the Option to the extent then vested and exercisable pursuant to Section 3 hereof as of the Termination Date, and not previously terminated in accordance with this Agreement, may be exercised within three months after the Termination Date, or on or prior to the Option Expiration Date as specified in the Stock Option Grant Notice, whichever is earlier, but may not be exercised thereafter except as set forth below. In such event, the unvested portion of the Option shall not be exercisable and shall expire and be cancelled on the Termination Date.

If this Option is designated in the Stock Option Grant Notice as an ISO and the Participant ceases to be an Employee of the Company or of an Affiliate but continues after termination of employment to provide service to the Company or an Affiliate as a director or Consultant, this Option shall continue to vest in accordance with Section 3 above as if this Option had not terminated until the Participant is no longer providing services to the Company. In such case, this Option shall automatically convert and be deemed a Nonstatutory Stock Option as of the date that is three months from termination of the Participant's employment and this Option shall continue on the same terms and conditions set forth herein until such Participant is no longer providing service to the Company or an Affiliate.

Notwithstanding the foregoing, in the event of the Participant's Disability or death within three months after the Termination Date, the Participant (or, in the case of death, the legal representative of the Participant's estate) may exercise the Option within one year after the Termination Date, but in no event after the Option Expiration Date as specified in the Stock Option Grant Notice.

In the event the Participant's service is terminated by the Company or an Affiliate for Cause, the Participant's right to exercise any unexercised portion of this Option even if vested shall cease immediately as of the time the Participant is notified his or her service is terminated for Cause, and this Option shall thereupon terminate. Notwithstanding anything herein to the contrary, if subsequent to the Participant's termination, but prior to the exercise of the Option, the Committee determines that, either prior or subsequent to the Participant's termination, the Participant engaged in conduct which would constitute Cause, then the Participant shall immediately cease to have any right to exercise the Option and this Option shall thereupon terminate.

In the event of the Disability of the Participant, as determined in accordance with the Plan, the Option shall be exercisable within one year after the Participant's termination of service due to Disability or, if earlier, on or prior to the Option Expiration Date as specified in the Stock Option Grant Notice. In such event, the Option shall be exercisable:

(a) to the extent that the Option has become exercisable but has not been exercised as of the date of the Participant's termination of service due to Disability; and

(b) in the event rights to exercise the Option accrue periodically, to the extent of a pro rata portion through the date of the Participant's termination of service due to Disability of any additional vesting rights that would have accrued on the next vesting date had the Participant not become Disabled. The proration shall be based upon the number of days accrued in the current vesting period prior to the date of the Participant's termination of service due to Disability provided that in no event shall any portion of the Option vest within one year of the date of grant.

In the event of the death of the Participant while an Employee, director or Consultant of the Company or of an Affiliate, the Option shall be exercisable by the legal representative of the Participant's estate within one year after the date of death of the Participant or, if earlier, on or prior to the Option Expiration Date as specified in the Stock Option Grant Notice. In such event, the Option shall be exercisable:

(x) to the extent that the Option has become exercisable but has not been exercised as of the date of death; and

(y) in the event rights to exercise the Option accrue periodically, to the extent of a pro rata portion through the date of death of any additional vesting, rights that would have accrued on the next vesting date had the Participant not died. The proration shall be based upon the number of days accrued in the current vesting period prior to the Participant's date of death provided that in no event shall any portion of the Option vest within one year of the date of grant.

5. METHOD OF EXERCISING OPTION.

Subject to the terms and conditions of this Agreement, the Option may be exercised by written notice to the Company or its designee, in substantially the form of Exhibit A attached hereto (or in such other form acceptable to the Company, which may include electronic notice). Such notice shall state the number of Shares with respect to which the Option is being exercised and shall be signed by the person exercising the Option (which signature may be provided electronically in a form acceptable to the Company). Payment of the Exercise Price for such Shares shall be made in accordance with Section 5(c) of the Plan. The Company shall deliver such Shares as soon as practicable after the notice shall be received, provided, however, that the Company may delay issuance of such Shares until completion of any action or obtaining of any consent, which the Company deems necessary under any applicable law. The Shares as to which the Option shall have been so exercised shall be issued to the Participant in the form of a book-entry account, for the benefit of the Participant or his or her designee, maintained by the Company's stock transfer agent or its designee. In the event the Option shall be exercised, pursuant to Section 4 hereof, by any person other than the Participant, such notice shall be accompanied by appropriate proof of the right of such person to exercise the Option. All Shares that shall be purchased upon the exercise of the Option as provided herein shall be fully paid and nonassessable.

6. PARTIAL EXERCISE.

Exercise of this Option to the extent above stated may be made in part at any time and from time to time within the above limits, except that no fractional share shall be issued pursuant to this Option.

7. NON-ASSIGNABILITY.

The Option shall not be transferable by the Participant otherwise than by will or by the laws of descent and distribution. If this Option is a Nonstatutory Stock Option then it may also be transferred pursuant to a qualified domestic relations order as defined by the Code or Title I of the Employee Retirement Income Security Act or the rules thereunder. Except as provided above in this paragraph, the Option shall be exercisable, during the Participant's lifetime, only by the Participant (or, in the event of legal incapacity or incompetency, by the Participant's guardian or representative) and shall not be assigned, pledged or hypothecated in any way (whether by operation of law or otherwise) and shall not be subject to execution, attachment or similar process. Any attempted transfer, assignment, pledge, hypothecation or other disposition of the Option or of any rights granted hereunder contrary to the provisions of this Section 7, or the levy of any attachment or similar process upon the Option shall be null and void.

8. NO RIGHTS AS STOCKHOLDER UNTIL EXERCISE.

The Participant shall have no rights as a stockholder with respect to Shares subject to this Agreement until entry of the Shares in the Company's book-entry account, in the name of the Participant or his or her designee, maintained by the Company's stock transfer agent or its designee. Except as is expressly provided in the Plan with respect to certain changes in the capitalization of the Company, no adjustment shall be made for dividends or similar rights for which the record date is prior to the date of such registration.

9. ADJUSTMENTS.

The Plan contains provisions covering the treatment of Options in a number of contingencies such as stock splits and mergers. Provisions in the Plan for adjustment with respect to stock subject to Options and the related provisions with respect to successors to the business of the Company are hereby made applicable hereunder and are incorporated herein by reference.

10. TAXES.

The Participant acknowledges and agrees that (i) any income or other taxes due from the Participant with respect to this Option or the Shares issuable pursuant to this Option shall be the Participant's responsibility; (ii) the Participant was free to use professional advisors of his or her choice in connection with this Agreement, has received advice from his or her professional advisors in connection with this Agreement, understands its meaning and import, and is entering into this Agreement freely and without coercion or duress; (iii) the Participant has not received and is not relying upon any advice, representations or assurances made by or on behalf of the Company or any Affiliate or any employee of or counsel to the Company or any Affiliate regarding any tax or other effects or implications of the Option, the Shares or other matters contemplated by this Agreement; and (iv) neither the Committee, the Company, its Affiliates, nor any of its officers or directors, shall be held liable for any applicable costs, taxes, or penalties associated with the Option if, in fact, the Internal Revenue Service were to determine that the Option constitutes deferred compensation under Section 409A of the Code.

If this Option is designated in the Stock Option Grant Notice as a Nonstatutory Stock Option or if the Option is an ISO and is converted into a Nonstatutory Stock Option and such Nonstatutory Stock Option is exercised, the Participant agrees that the Company may withhold from the Participant's remuneration, if any, the minimum statutory amount of federal, state and local withholding taxes attributable to such amount that is considered compensation includable in such person's gross income. At the Company's discretion, and to the extent permitted by applicable law, the Participant agrees that the amount required to be withheld may be withheld in cash from such remuneration, or in kind from the Shares otherwise deliverable to the Participant on exercise of the Option. The Participant further agrees that, if the Company does not withhold an amount from the Participant's remuneration sufficient to satisfy the Company's income tax withholding obligation, the Participant will reimburse the Company on demand, in cash, for the amount under-withheld and if reimbursement is not permissible under applicable law, the Participant will deliver sufficient funds to satisfy any withholding obligation in advance of, or simultaneous with, the exercise of the Option and the Company is not required to recognize the exercise of any such Option to the extent the withholding obligations have not been so satisfied.

11. PURCHASE FOR INVESTMENT.

Unless the offering and sale of the Shares to be issued upon the particular exercise of the Option shall have been effectively registered under the Securities Act, the Company shall be under no obligation to issue the Shares covered by such exercise unless the Company has determined that such exercise and issuance would be exempt from the registration requirements of the Securities Act and until the following conditions have been fulfilled:

(a) The person(s) who exercise the Option shall warrant to the Company, at the time of such exercise, that such person(s) are acquiring such Shares for their own respective accounts, for investment, and not with a view to, or for sale in connection with, the distribution of any such Shares, in which event the person(s) acquiring such Shares shall be bound by the provisions of the following legend which shall be endorsed upon any certificate(s) evidencing the Shares issued pursuant to such exercise:

"The shares represented by this certificate have been taken for investment and they may not be sold or otherwise transferred by any person, including a pledgee, unless (1) either (a) a Registration Statement with respect to such shares shall be effective under the Securities Act of 1933, as amended, or (b) the Company shall have received an opinion of counsel satisfactory to it that an exemption from registration under such Act is then available, and (2) there shall have been compliance with all applicable state securities laws;" and

(b) If the Company so requires, the Company shall have received an opinion of its counsel that the Shares may be issued upon such particular exercise in compliance with the Securities Act without registration thereunder. Without limiting the generality of the foregoing, the Company may delay issuance of the Shares until completion of any action or obtaining of any consent, which the Company deems necessary under any applicable law (including without limitation state securities or "blue sky" laws).

12. NO OBLIGATION TO MAINTAIN RELATIONSHIP.

The Participant acknowledges that: (i) the Company is not by the Plan or this Option obligated to continue the Participant as an employee, director or Consultant of the Company or an Affiliate; (ii) the Plan is discretionary in nature and may be suspended or terminated by the Company at any time; (iii) the grant of the Option is a one-time benefit which does not create any contractual or other right to receive future grants of options, or benefits in lieu of options; (iv) all determinations with respect to any such future grants, including, but not limited to, the times when options shall be granted, the number of shares subject to each option, the option price, and the time or times when each option shall be exercisable, will be at the sole discretion of the Company; (v) the Participant's participation in the Plan is voluntary; (vi) the value of the Option is an extraordinary item of compensation which is outside the scope of the Participant's employment or consulting contract, if any; and (vii) the Option is not part of normal or expected compensation for purposes of calculating any severance, resignation, redundancy, end of service payments, bonuses, long-service awards, pension or retirement benefits or similar payments.

13. IF OPTION IS INTENDED TO BE AN ISO.

If this Option is designated in the Stock Option Grant Notice as an ISO so that the Participant (or, in the case of death, the legal representative of the Participant's estate) may qualify for the favorable tax treatment provided to holders of Options that meet the standards of Section 422 of the Code then any provision of this Agreement or the Plan which conflicts with the Code so that this Option would not be deemed an ISO is null and void and any ambiguities shall be resolved so that the Option qualifies as an ISO. The Participant should consult with the Participant's own tax advisors regarding the tax effects of the Option and the requirements necessary to obtain favorable tax treatment under Section 422 of the Code, including, but not limited to, holding period requirements.

Notwithstanding the foregoing, to the extent that the Option is designated in the Stock Option Grant Notice as an ISO and is not deemed to be an ISO pursuant to Section 422(d) of the Code because the aggregate Fair Market Value (determined as of the Date of Option Grant) of any of the Shares with respect to which this ISO is granted becomes exercisable for the first time during any calendar year in excess of $100,000, the portion of the Option representing such excess value shall be treated as a Nonstatutory Stock Option and the Participant shall be deemed to have taxable income measured by the difference between the then Fair Market Value of the Shares received upon exercise and the price paid for such Shares pursuant to this Agreement.

Neither the Company nor any Affiliate shall have any liability to the Participant, or any other party, if the Option (or any part thereof) that is intended to be an ISO is not an ISO or for any action taken by the Committee, including without limitation the conversion of an ISO to a Nonstatutory Stock Option.

14. NOTICE TO COMPANY OF DISQUALIFYING DISPOSITION OF AN ISO.

If this Option is designated in the Stock Option Grant Notice as an ISO then the Participant agrees to notify the Company in writing immediately after the Participant makes a Disqualifying Disposition of any of the Shares acquired pursuant to the exercise of the ISO. A Disqualifying Disposition is defined in Section 424(c) of the Code and includes any disposition (including any sale) of such Shares before the later of (a) two years after the date the Participant was granted the ISO or (b) one year after the date the Participant acquired Shares by exercising the ISO, except as otherwise provided in Section 424(c) of the Code. If the Participant has died before the Shares are sold, these holding period requirements do not apply and no Disqualifying Disposition can occur thereafter.

15. NOTICES.

Any notices required or permitted by the terms of this Agreement or the Plan shall he given by recognized courier service, facsimile, registered or certified mail, return receipt requested, addressed as follows:

If to the Company:

Xenetic Biosciences, Inc.
40 Speen Street, Ste 102
Framingham, MA 01701
Attention: CFO

If to the Participant, at the address set forth on the Stock Option Grant Notice.

or to such other address or addresses of which notice in the same manner has previously been given. Any such notice shall be deemed to have been given upon the earlier of receipt, one business day following delivery to a recognized courier service or three business days following mailing by registered or certified mail.

16. GOVERNING LAW.

This Agreement shall be governed by and construed in accordance with the laws of Delaware, without giving effect to the conflict of law principles thereof. For the purpose of litigating any dispute that arises under this Agreement, the parties hereby consent to exclusive jurisdiction in Delaware and agree that such litigation shall be conducted in the state courts of Delaware or the federal courts of the United States located in Delaware.

17. BENEFIT OF AGREEMENT,

Subject to the provisions of the Plan and the other provisions hereof, this Agreement shall be for the benefit of and shall be binding upon the heirs, executors, administrators, successors and assigns of the parties hereto.

18. ENTIRE AGREEMENT.

This Agreement, together with the Plan, embodies the entire agreement and understanding between the parties hereto with respect to the subject matter hereof and supersedes all prior oral or written agreements and understandings relating to the subject matter hereof. No statement, representation, warranty, covenant or agreement not expressly set forth in this Agreement shall affect or be used to interpret, change or restrict, the express terms and provisions of this Agreement, provided however, in any event, this Agreement shall be subject to and governed by the Plan.

19. MODIFICATIONS AND AMENDMENTS.

The terms and provisions of this Agreement may be modified or amended as provided in the Plan.

20. WAIVERS AND CONSENTS.

Except as provided in the Plan, the terms and provisions of this Agreement may be waived, or consent for the departure therefrom granted, only by written document executed by the party entitled to the benefits of such terms or provisions. No such waiver or consent shall be deemed to be or shall constitute a waiver or consent with respect to any other terms or provisions of this Agreement, whether or not similar. Each such waiver or consent shall be effective only in the specific instance and for the purpose for which it was given, and shall not constitute a continuing waiver or consent.

21. DATA PRIVACY.

By entering into this Agreement, the Participant: (i) authorizes the Company and each Affiliate, and any agent of the Company or any Affiliate administering the Plan or providing Plan recordkeeping services, to disclose to the Company or any of its Affiliates such information and data as the Company or any such Affiliate shall request in order to facilitate the grant of options and the administration of the Plan; and (ii) authorizes the Company and each Affiliate to store and transmit such information in electronic form for the purposes set forth in this Agreement.

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Exhibit A

NOTICE OF EXERCISE OF STOCK OPTION

[Form for Shares registered in the United States]

To: Xenetic Biosciences, Inc.

Ladies and Gentlemen:

I hereby exercise my Stock Option to purchase _____ shares (the "Shares") of the common stock, $0.001 par value, of Xenetic Biosciences, Inc. (the "Company"), at the exercise price of $_____ per share, pursuant to and subject to the terms of that Stock Option Grant Notice dated _____, 20___.

I understand the nature of the investment I am making and the financial risks thereof. I am aware that it is my responsibility to have consulted with competent tax and legal advisors about the relevant national, state and local income tax and securities laws affecting the exercise of the Option and the purchase and subsequent sale of the Shares.

I am paying the option exercise price for the Shares as follows:

_____

Please issue the Shares (cheek one):

[_] to me; or

[_] to me and _____, as joint tenants with right of survivorship,

at the following address:

_____
_____
_____

My mailing address for stockholder communications, if different from the address listed above, is:

_____
_____
_____

Very truly yours,

_____
Participant

_____
Print Name

_____
Date

Exhibit 10.53

Option No. 131

XENETIC BIOSCIENCES, INC.

Stock Option Grant Notice
Stock Option Grant under the
Amended and Restated Xenetic Biosciences, Inc.
Equity Incentive Plan, adopted by the Board of Directors on September 26, 2019 and approved by stockholders on December 4, 2019

1.	Name and Address of Participant:	Jeffrey Eisenberg c/o Xenetic Biosciences, Inc. 40 Speen Street, Framingham, MA 01701
2.	Date of Option Grant:	December 4, 2019
3.	Type of Grant:	ISO to the extent qualified
4.	Maximum Number of Shares for which this Option is exercisable:	230,000
5.	Exercise (purchase) price per share:	$1.31
6.	Option Expiration Date:	December 4, 2029
7.	Vesting Start Date:	December 4, 2019

8. Vesting Schedule: This Option shall become exercisable (and the Shares issued upon exercise shall be vested) as follows provided the Participant is an Eligible Employee, director or Consultant of the Company or of an Affiliate on the applicable vesting date:

76,666 shares shall vest on the first anniversary of the Vesting Start Date
76,667 shares shall vest on the second anniversary of the Vesting Start Date
76,667 shares shall vest on the third anniversary of the Vesting Start Date

The foregoing rights are cumulative and are subject to the other terms and conditions of the Agreement and the Amended and Restated Xenetic Biosciences, Inc. Equity Incentive Plan adopted by the Board of Directors on September 26, 2019 and approved by stockholders on December 4, 2019, as amended from time to time (the "Plan"). Notwithstanding anything to the contrary in the Agreement or the Plan, this Option may be exercised at any time during the twelve month period following the termination of the Participant's employment with the Company other than for "Cause" (as defined in the Employment Agreement between the Company and the Participant entered into on October 26, 2017 (the "Employment Agreement")), but in no event later than the Option Expiration Date. Any Option not exercised on the later of such dates described in the preceding sentence shall be forfeited and canceled as of such later date.

Notwithstanding the foregoing or any terms in the Agreement or the Plan to the contrary, in the event of a Change in Control (as defined in the Plan), all of the Shares which would have vested in each vesting installment(s) remaining under this Option will be vested and exercisable upon the Change in Control.

Notwithstanding the foregoing or any terms in the Agreement or the Plan to the contrary, in the event of a termination of the Participant's employment with the Company by the Company other than for "Cause" or by the Participant for "Good Reason" (in each case, as defined in the Employment Agreement), all of the Shares which would have vested in each vesting installment(s) remaining under this Options will be vested immediately prior to such termination provided that in no event shall any portion of the Option vest within one year of the date of grant unless such termination is within twelve months following a Change in Control.

Notwithstanding the foregoing, unless otherwise approved by the Administrator in its sole discretion, the Option shall only be exercised from and after the date the Company has filed a Form S-8 registration statement with the U.S. Securities and Exchange Commission covering the Shares authorized under the Plan.

The Company and the Participant acknowledge receipt of this Stock Option Grant Notice and agree to the terms of the Stock Option Agreement Incorporated Terms and Conditions (attached hereto and incorporated by reference herein (the "Agreement")), the Plan and the terms of this Option Grant as set forth above.

XENETIC BIOSCIENCES, INC.

By: /s/ James Parslow
Name: James Parslow
Title: Chief Financial Officer

/s/ Jeffrey Eisenberg
Participant

XENETIC BIOSCIENCES, INC.

STOCK OPTION AGREEMENT - INCORPORATED TERMS AND CONDITIONS

AGREEMENT made as of the date of grant set forth in the Stock Option Grant Notice by and between Xenetic Biosciences, Inc. (the "Company"), a Nevada corporation, and the individual whose name appears on the Stock Option Grant Notice (the "Participant").

WHEREAS, the Company desires to grant to the Participant an Option to purchase shares of its common stock, $0.001 par value per share (the "Shares"), under and for the purposes set forth in the Amended and Restated Xenetic BioSciences, Inc. Equity Incentive Plan, adopted by the Board of Directors on September 26, 2019 and adopted by stockholders on December 4, 2019, as amended from time to time (the "Plan"), and any rules and regulations promulgated by the Committee with respect to the Plan;

WHEREAS, the Company and the Participant understand and agree that any terms used and not defined herein have the same meanings as in the Plan; and

WHEREAS, the Company and the Participant each intend that the Option granted herein shall be of the type set forth in the Stock Option Grant Notice.

NOW, THEREFORE, in consideration of the mutual covenants hereinafter set forth and for other good and valuable consideration, the parties hereto agree as follows:

1. GRANT OF OPTION.

The Company hereby grants to the Participant the right and option to purchase all or any part of an aggregate of the number of Shares set forth in the Stock Option Grant Notice, on the terms and conditions and subject to all the limitations set forth therein and herein (collectively, the "Agreement"), under United States securities and tax laws, and in the Plan, which is incorporated herein by reference. The Participant acknowledges receipt of a copy of the Plan.

2. EXERCISE PRICE.

The exercise price of the Shares covered by the Option shall be the amount per Share set forth in the Stock Option Grant Notice, subject to adjustment, as provided in the Plan, in the event of a stock split, reverse stock split or other events affecting the holders of Shares after the date hereof (the "Exercise Price"). Payment shall be made in accordance with Section 5(c) of the Plan.

3. EXERCISABILITY OF OPTION.

Subject to the terms and conditions set forth in this Agreement and the Plan, the Option granted hereby shall become vested and exercisable as set forth in the Stock Option Grant Notice and is subject to the other terms and conditions of this Agreement and the Plan.

4. TERM OF OPTION.

This Option shall terminate on the Option Expiration Date as specified in the Stock Option Grant Notice and, if this Option is designated in the Stock Option Grant Notice as an Incentive Stock Option (an "ISO") and the Participant is a 10% Stockholder, such date may not be more than five years from the date of this Agreement, but shall be subject to earlier termination as provided herein or in the Plan.

If the Participant ceases to be an Employee, director or Consultant of the Company or of an Affiliate for any reason other than the death or Disability of the Participant, or termination of the Participant for Cause (the "Termination Date"), the Option to the extent then vested and exercisable pursuant to Section 3 hereof as of the Termination Date, and not previously terminated in accordance with this Agreement, may be exercised within three months after the Termination Date, or on or prior to the Option Expiration Date as specified in the Stock Option Grant Notice, whichever is earlier, but may not be exercised thereafter except as set forth below. In such event, the unvested portion of the Option shall not be exercisable and shall expire and be cancelled on the Termination Date.

If this Option is designated in the Stock Option Grant Notice as an ISO and the Participant ceases to be an Employee of the Company or of an Affiliate but continues after termination of employment to provide service to the Company or an Affiliate as a director or Consultant, this Option shall continue to vest in accordance with Section 3 above as if this Option had not terminated until the Participant is no longer providing services to the Company. In such case, this Option shall automatically convert and be deemed a Nonstatutory Stock Option as of the date that is three months from termination of the Participant's employment and this Option shall continue on the same terms and conditions set forth herein until such Participant is no longer providing service to the Company or an Affiliate.

Notwithstanding the foregoing, in the event of the Participant's Disability or death within three months after the Termination Date, the Participant (or, in the case of death, the legal representative of the Participant's estate) may exercise the Option within one year after the Termination Date, but in no event after the Option Expiration Date as specified in the Stock Option Grant Notice.

In the event the Participant's service is terminated by the Company or an Affiliate for Cause, the Participant's right to exercise any unexercised portion of this Option even if vested shall cease immediately as of the time the Participant is notified his or her service is terminated for Cause, and this Option shall thereupon terminate. Notwithstanding anything herein to the contrary, if subsequent to the Participant's termination, but prior to the exercise of the Option, the Committee determines that, either prior or subsequent to the Participant's termination, the Participant engaged in conduct which would constitute Cause, then the Participant shall immediately cease to have any right to exercise the Option and this Option shall thereupon terminate.

In the event of the Disability of the Participant, as determined in accordance with the Plan, the Option shall be exercisable within one year after the Participant's termination of service due to Disability or, if earlier, on or prior to the Option Expiration Date as specified in the Stock Option Grant Notice. In such event, the Option shall be exercisable:

(a) to the extent that the Option has become exercisable but has not been exercised as of the date of the Participant's termination of service due to Disability; and

(b) in the event rights to exercise the Option accrue periodically, to the extent of a pro rata portion through the date of the Participant's termination of service due to Disability of any additional vesting rights that would have accrued on the next vesting date had the Participant not become Disabled. The proration shall be based upon the number of days accrued in the current vesting period prior to the date of the Participant's termination of service due to Disability provided that in no event shall any portion of the Option vest within one year of the date of grant.

In the event of the death of the Participant while an Employee, director or Consultant of the Company or of an Affiliate, the Option shall be exercisable by the legal representative of the Participant's estate within one year after the date of death of the Participant or, if earlier, on or prior to the Option Expiration Date as specified in the Stock Option Grant Notice. In such event, the Option shall be exercisable:

(x) to the extent that the Option has become exercisable but has not been exercised as of the date of death; and

(y) in the event rights to exercise the Option accrue periodically, to the extent of a pro rata portion through the date of death of any additional vesting, rights that would have accrued on the next vesting date had the Participant not died. The proration shall be based upon the number of days accrued in the current vesting period prior to the Participant's date of death provided that in no event shall any portion of the Option vest within one year of the date of grant.

5. METHOD OF EXERCISING OPTION.

Subject to the terms and conditions of this Agreement, the Option may be exercised by written notice to the Company or its designee, in substantially the form of Exhibit A attached hereto (or in such other form acceptable to the Company, which may include electronic notice). Such notice shall state the number of Shares with respect to which the Option is being exercised and shall be signed by the person exercising the Option (which signature may be provided electronically in a form acceptable to the Company). Payment of the Exercise Price for such Shares shall be made in accordance with Section 5(c) of the Plan. The Company shall deliver such Shares as soon as practicable after the notice shall be received, provided, however, that the Company may delay issuance of such Shares until completion of any action or obtaining of any consent, which the Company deems necessary under any applicable law. The Shares as to which the Option shall have been so exercised shall be issued to the Participant in the form of a book-entry account, for the benefit of the Participant or his or her designee, maintained by the Company's stock transfer agent or its designee. In the event the Option shall be exercised, pursuant to Section 4 hereof, by any person other than the Participant, such notice shall be accompanied by appropriate proof of the right of such person to exercise the Option. All Shares that shall be purchased upon the exercise of the Option as provided herein shall be fully paid and nonassessable.

6. PARTIAL EXERCISE.

Exercise of this Option to the extent above stated may be made in part at any time and from time to time within the above limits, except that no fractional share shall be issued pursuant to this Option.

7. NON-ASSIGNABILITY.

The Option shall not be transferable by the Participant otherwise than by will or by the laws of descent and distribution. If this Option is a Nonstatutory Stock Option then it may also be transferred pursuant to a qualified domestic relations order as defined by the Code or Title I of the Employee Retirement Income Security Act or the rules thereunder. Except as provided above in this paragraph, the Option shall be exercisable, during the Participant's lifetime, only by the Participant (or, in the event of legal incapacity or incompetency, by the Participant's guardian or representative) and shall not be assigned, pledged or hypothecated in any way (whether by operation of law or otherwise) and shall not be subject to execution, attachment or similar process. Any attempted transfer, assignment, pledge, hypothecation or other disposition of the Option or of any rights granted hereunder contrary to the provisions of this Section 7, or the levy of any attachment or similar process upon the Option shall be null and void.

8. NO RIGHTS AS STOCKHOLDER UNTIL EXERCISE.

The Participant shall have no rights as a stockholder with respect to Shares subject to this Agreement until entry of the Shares in the Company's book-entry account, in the name of the Participant or his or her designee, maintained by the Company's stock transfer agent or its designee. Except as is expressly provided in the Plan with respect to certain changes in the capitalization of the Company, no adjustment shall be made for dividends or similar rights for which the record date is prior to the date of such registration.

9. ADJUSTMENTS.

The Plan contains provisions covering the treatment of Options in a number of contingencies such as stock splits and mergers. Provisions in the Plan for adjustment with respect to stock subject to Options and the related provisions with respect to successors to the business of the Company are hereby made applicable hereunder and are incorporated herein by reference.

10. TAXES.

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The Participant acknowledges and agrees that (i) any income or other taxes due from the Participant with respect to this Option or the Shares issuable pursuant to this Option shall be the Participant's responsibility; (ii) the Participant was free to use professional advisors of his or her choice in connection with this Agreement, has received advice from his or her professional advisors in connection with this Agreement, understands its meaning and import, and is entering into this Agreement freely and without coercion or duress; (iii) the Participant has not received and is not relying upon any advice, representations or assurances made by or on behalf of the Company or any Affiliate or any employee of or counsel to the Company or any Affiliate regarding any tax or other effects or implications of the Option, the Shares or other matters contemplated by this Agreement; and (iv) neither the Committee, the Company, its Affiliates, nor any of its officers or directors, shall be held liable for any applicable costs, taxes, or penalties associated with the Option if, in fact, the Internal Revenue Service were to determine that the Option constitutes deferred compensation under Section 409A of the Code.

If this Option is designated in the Stock Option Grant Notice as a Nonstatutory Stock Option or if the Option is an ISO and is converted into a Nonstatutory Stock Option and such Nonstatutory Stock Option is exercised, the Participant agrees that the Company may withhold from the Participant's remuneration, if any, the minimum statutory amount of federal, state and local withholding taxes attributable to such amount that is considered compensation includable in such person's gross income. At the Company's discretion, and to the extent permitted by applicable law, the Participant agrees that the amount required to be withheld may be withheld in cash from such remuneration, or in kind from the Shares otherwise deliverable to the Participant on exercise of the Option. The Participant further agrees that, if the Company does not withhold an amount from the Participant's remuneration sufficient to satisfy the Company's income tax withholding obligation, the Participant will reimburse the Company on demand, in cash, for the amount under-withheld and if reimbursement is not permissible under applicable law, the Participant will deliver sufficient funds to satisfy any withholding obligation in advance of, or simultaneous with, the exercise of the Option and the Company is not required to recognize the exercise of any such Option to the extent the withholding obligations have not been so satisfied.

11. PURCHASE FOR INVESTMENT.

Unless the offering and sale of the Shares to be issued upon the particular exercise of the Option shall have been effectively registered under the Securities Act, the Company shall be under no obligation to issue the Shares covered by such exercise unless the Company has determined that such exercise and issuance would be exempt from the registration requirements of the Securities Act and until the following conditions have been fulfilled:

(a) The person(s) who exercise the Option shall warrant to the Company, at the time of such exercise, that such person(s) are acquiring such Shares for their own respective accounts, for investment, and not with a view to, or for sale in connection with, the distribution of any such Shares, in which event the person(s) acquiring such Shares shall be bound by the provisions of the following legend which shall be endorsed upon any certificate(s) evidencing the Shares issued pursuant to such exercise:

"The shares represented by this certificate have been taken for investment and they may not be sold or otherwise transferred by any person, including a pledgee, unless (1) either (a) a Registration Statement with respect to such shares shall be effective under the Securities Act of 1933, as amended, or (b) the Company shall have received an opinion of counsel satisfactory to it that an exemption from registration under such Act is then available, and (2) there shall have been compliance with all applicable state securities laws;" and

(b) If the Company so requires, the Company shall have received an opinion of its counsel that the Shares may be issued upon such particular exercise in compliance with the Securities Act without registration thereunder. Without limiting the generality of the foregoing, the Company may delay issuance of the Shares until completion of any action or obtaining of any consent, which the Company deems necessary under any applicable law (including without limitation state securities or "blue sky" laws).

12. NO OBLIGATION TO MAINTAIN RELATIONSHIP.

The Participant acknowledges that: (i) the Company is not by the Plan or this Option obligated to continue the Participant as an employee, director or Consultant of the Company or an Affiliate; (ii) the Plan is discretionary in nature and may be suspended or terminated by the Company at any time; (iii) the grant of the Option is a one-time benefit which does not create any contractual or other right to receive future grants of options, or benefits in lieu of options; (iv) all determinations with respect to any such future grants, including, but not limited to, the times when options shall be granted, the number of shares subject to each option, the option price, and the time or times when each option shall be exercisable, will be at the sole discretion of the Company; (v) the Participant's participation in the Plan is voluntary; (vi) the value of the Option is an extraordinary item of compensation which is outside the scope of the Participant's employment or consulting contract, if any; and (vii) the Option is not part of normal or expected compensation for purposes of calculating any severance, resignation, redundancy, end of service payments, bonuses, long-service awards, pension or retirement benefits or similar payments.

13. IF OPTION IS INTENDED TO BE AN ISO.

If this Option is designated in the Stock Option Grant Notice as an ISO so that the Participant (or, in the case of death, the legal representative of the Participant's estate) may qualify for the favorable tax treatment provided to holders of Options that meet the standards of Section 422 of the Code then any provision of this Agreement or the Plan which conflicts with the Code so that this Option would not be deemed an ISO is null and void and any ambiguities shall be resolved so that the Option qualifies as an ISO. The Participant should consult with the Participant's own tax advisors regarding the tax effects of the Option and the requirements necessary to obtain favorable tax treatment under Section 422 of the Code, including, but not limited to, holding period requirements.

Notwithstanding the foregoing, to the extent that the Option is designated in the Stock Option Grant Notice as an ISO and is not deemed to be an ISO pursuant to Section 422(d) of the Code because the aggregate Fair Market Value (determined as of the Date of Option Grant) of any of the Shares with respect to which this ISO is granted becomes exercisable for the first time during any calendar year in excess of $100,000, the portion of the Option representing such excess value shall be treated as a Nonstatutory Stock Option and the Participant shall be deemed to have taxable income measured by the difference between the then Fair Market Value of the Shares received upon exercise and the price paid for such Shares pursuant to this Agreement.

Neither the Company nor any Affiliate shall have any liability to the Participant, or any other party, if the Option (or any part thereof) that is intended to be an ISO is not an ISO or for any action taken by the Committee, including without limitation the conversion of an ISO to a Nonstatutory Stock Option.

14. NOTICE TO COMPANY OF DISQUALIFYING DISPOSITION OF AN ISO.

If this Option is designated in the Stock Option Grant Notice as an ISO then the Participant agrees to notify the Company in writing immediately after the Participant makes a Disqualifying Disposition of any of the Shares acquired pursuant to the exercise of the ISO. A Disqualifying Disposition is defined in Section 424(c) of the Code and includes any disposition (including any sale) of such Shares before the later of (a) two years after the date the Participant was granted the ISO or (b) one year after the date the Participant acquired Shares by exercising the ISO, except as otherwise provided in Section 424(c) of the Code. If the Participant has died before the Shares are sold, these holding period requirements do not apply and no Disqualifying Disposition can occur thereafter.

15. NOTICES.

Any notices required or permitted by the terms of this Agreement or the Plan shall he given by recognized courier service, facsimile, registered or certified mail, return receipt requested, addressed as follows:

If to the Company:

Xenetic Biosciences, Inc.
40 Speen Street, Ste 102
Framingham, MA 01701
Attention: CFO

If to the Participant, at the address set forth on the Stock Option Grant Notice.

or to such other address or addresses of which notice in the same manner has previously been given. Any such notice shall be deemed to have been given upon the earlier of receipt, one business day following delivery to a recognized courier service or three business days following mailing by registered or certified mail.

16. GOVERNING LAW.

This Agreement shall be governed by and construed in accordance with the laws of Delaware, without giving effect to the conflict of law principles thereof. For the purpose of litigating any dispute that arises under this Agreement, the parties hereby consent to exclusive jurisdiction in Delaware and agree that such litigation shall be conducted in the state courts of Delaware or the federal courts of the United States located in Delaware.

17. BENEFIT OF AGREEMENT,

Subject to the provisions of the Plan and the other provisions hereof, this Agreement shall be for the benefit of and shall be binding upon the heirs, executors, administrators, successors and assigns of the parties hereto.

18. ENTIRE AGREEMENT.

This Agreement, together with the Plan, embodies the entire agreement and understanding between the parties hereto with respect to the subject matter hereof and supersedes all prior oral or written agreements and understandings relating to the subject matter hereof. No statement, representation, warranty, covenant or agreement not expressly set forth in this Agreement shall affect or be used to interpret, change or restrict, the express terms and provisions of this Agreement, provided however, in any event, this Agreement shall be subject to and governed by the Plan.

19. MODIFICATIONS AND AMENDMENTS.

The terms and provisions of this Agreement may be modified or amended as provided in the Plan.

20. WAIVERS AND CONSENTS.

Except as provided in the Plan, the terms and provisions of this Agreement may be waived, or consent for the departure therefrom granted, only by written document executed by the party entitled to the benefits of such terms or provisions. No such waiver or consent shall be deemed to be or shall constitute a waiver or consent with respect to any other terms or provisions of this Agreement, whether or not similar. Each such waiver or consent shall be effective only in the specific instance and for the purpose for which it was given, and shall not constitute a continuing waiver or consent.

21. DATA PRIVACY.

By entering into this Agreement, the Participant: (i) authorizes the Company and each Affiliate, and any agent of the Company or any Affiliate administering the Plan or providing Plan recordkeeping services, to disclose to the Company or any of its Affiliates such information and data as the Company or any such Affiliate shall request in order to facilitate the grant of options and the administration of the Plan; and (ii) authorizes the Company and each Affiliate to store and transmit such information in electronic form for the purposes set forth in this Agreement.

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Exhibit A

NOTICE OF EXERCISE OF STOCK OPTION

[Form for Shares registered in the United States]

To: Xenetic Biosciences, Inc.

Ladies and Gentlemen:

I hereby exercise my Stock Option to purchase _____ shares (the "Shares") of the common stock, $0.001 par value, of Xenetic Biosciences, Inc. (the "Company"), at the exercise price of $_____ per share, pursuant to and subject to the terms of that Stock Option Grant Notice dated _____, 20___.

I understand the nature of the investment I am making and the financial risks thereof. I am aware that it is my responsibility to have consulted with competent tax and legal advisors about the relevant national, state and local income tax and securities laws affecting the exercise of the Option and the purchase and subsequent sale of the Shares.

I am paying the option exercise price for the Shares as follows:

_____

Please issue the Shares (cheek one):

[_] to me; or

[_] to me and _____, as joint tenants with right of survivorship,

at the following address:

_____
_____
_____

My mailing address for stockholder communications, if different from the address listed above, is:

_____
_____
_____

Very truly yours,

_____
Participant

_____
Print Name

_____
Date

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 Bioscience, Inc.	Delaware
SymbioTec, GmbH	German registered company
Hesperix S.A.	Swiss 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), on Form S-3 (File Nos. 333-227572 and 333-233769) of our report dated March 26, 2020, with respect to our audits of the consolidated financial statements of Xenetic Biosciences, Inc. as of December 31, 2019 and 2018 and for each of the two years in the period ended December 31, 2019, which report is included in this Annual Report on Form 10-K of Xenetic Biosciences, Inc. for the year ended December 31, 2019.

/s/ Marcum LLP

Marcum LLP
Boston, Massachusetts
March 26, 2020

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 26, 2020

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 26, 2020

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, 2019, 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 26, 2020

/s/ Jeffrey F. Eisenberg
Jeffrey F. Eisenberg
Chief Executive Officer
(Principal Executive Officer)

/s/James Parslow
James Parslow
Chief Financial Officer
(Principal Financial Officer)