As filed with the Securities and Exchange Commission on May 15, 2019

Registration No. 333-_____

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

FORM S-1
REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

XENETIC BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

Nevada	**2834**	**45-2952962**
(State or other jurisdiction of incorporation or organization)	*(Primary Standard Industrial Classification Code Number)*	*(I.R.S. Employer Identification Number)*

40 Speen Street, Suite 102
Framingham, Massachusetts
(781) 778-7720
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

James F. Parslow
Chief Financial Officer
40 Speen Street, Suite 102
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(781) 778-7720
(Name, address, including zip code, and telephone number including area code, of agent for service)

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Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. ☐

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

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

Large accelerated filer ☐
Non-accelerated filer ☐

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 7(a)(2)(B) of the Securities Act. ☐

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Proposed maximum aggregate offering price [1]	Amount of registration fee [2]
Common stock, $0.001 par value per share	$17,500,000 [3]	$2,121

(1) Includes the public offering price of shares that the underwriters have the option to purchase to cover overallotments, if any. Estimated solely for the purpose of calculating the amount of the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended.
(2) Calculated pursuant to Rule 457(o) based on an estimate of the proposed maximum aggregate initial public offering price.
(3) Includes the underwriters option to purchase up to an additional [●] shares from us at the public offering price, less underwriting discounts and commissions, within 45 days after the date of this prospectus.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act, or until the registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

Subject to completion, dated May 15, 2019

The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell nor does it seek an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

[●] Shares

Xenetic Biosciences, Inc.

Common Stock

This is a firm commitment offering of [●] shares of common stock, par value $0.001 per share, of Xenetic Biosciences, Inc., a Nevada corporation.

Our common stock is listed for trading on The NASDAQ Capital Market ("NASDAQ") under the symbol "XBIO." As of May 14, 2019, the last reported sale price of our common stock on NASDAQ was $1.16.

	Per share	Total
Public offering price	$	$
Underwriting discounts and commissions(1)	$	$
Proceeds to Xenetic Biosciences, Inc., before expenses	$	$

(1) The underwriters will receive compensation in addition to the underwriting discount. We have also agreed to reimburse the underwriters for certain expenses. See "Underwriting" beginning on page **[●]**.

The underwriters have the option to purchase up to an additional shares from us at the public offering price, less the underwriting discounts and commissions, within 45 days after the date of this prospectus to cover overallotments, if any.

Investing in our common stock involves a high degree of risk. See "Risk Factors," beginning on page [●].

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The underwriters expect to deliver the shares of common stock to investors on or about , 2019.

Sole Book-Running Manager

Maxim Group LLC

The date of this prospectus is , 2019.

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We have not authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectuses we have prepared. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the shares offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus is current only as of its date.

For investors outside the United States: We have not, and the underwriters have not, done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than the United States. Persons outside of the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this prospectus outside of the United States.

PROSPECTUS SUMMARY

This summary highlights selected information contained elsewhere in this prospectus and does not contain all the information that you should consider before making your investment decision. Before investing in our common stock, you should carefully read this entire prospectus, including the information set forth under the "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of this prospectus and our consolidated financial statements and the accompanying notes included in this prospectus. Except as otherwise indicated herein or as the context otherwise requires, references in this prospectus to "Xenetic," the "Company," "we," "us," and "our" refer to Xenetic Biosciences, Inc. and our consolidated subsidiaries.

Overview

We are a clinical stage biopharmaceutical company focused on the discovery, research and development of next-generation biological drugs and novel oncology therapeutics. We have an extensive patent portfolio of over 170 issued patents in the U.S. and worldwide, covering various aspects of our PolyXen™ platform technology and advanced polymer conjugate technologies, as well as our proprietary biologic drugs and novel oncology drug candidates. We believe our portfolio positions us well for strategic partnership and commercialization opportunities. Our objective is to leverage our portfolio to maximize opportunities to out-license assets from our portfolio in order to generate working capital to both build long-term stockholder value and provide us with the funding necessary for clinical development of our oncology drug candidates through market launch.

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

Our most advanced investigational drug candidate is oncology therapeutic XBIO-101 (sodium cridanimod) for the treatment of progestin resistant endometrial cancer. We have exclusive rights to develop and commercialize XBIO-101 worldwide, except for specified countries in the Commonwealth of Independent States ("CIS"). XBIO-101 has been granted orphan drug designation by the U.S. Food and Drug Administration ("FDA") for the potential treatment of progesterone receptor negative ("PrR-") endometrial cancer in conjunction with progesterone therapy. We commenced a Phase II trial for XBIO-101 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.

Our lead proprietary technology is PolyXen™, 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. 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. Although we hold a broad patent portfolio, because of capital constraints the focus of our internal development efforts in 2018 was limited to research and development of our primary product candidate XBIO-101.

We were incorporated under the laws of the State of Nevada in August 2011. We, directly or indirectly, through our wholly-owned subsidiary, Xenetic 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 OncoHist™, PolyXen, ErepoXen™ and ImuXen™.

Our Strategy

We recently announced our plans to acquire the XCART platform, a novel CAR T technology engineered to target patient- and tumor-specific neoantigens (referred to herein as "XCART") (See Recent Developments for a description of the transaction and technology.) The acquisition of the platform technology is expected to close in the first half of 2019, and the Company plans to initially apply the XCART technology to develop cell-based therapeutics for the treatment of B-cell Lymphomas. 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 anticipate that our primary focus once the transaction is completed will be on advancing this technology through regulatory approval and commercialization.

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

We intend to pursue orphan drug designations 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 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 the Company in the form of access to partner-generated clinical data, which is informative when contemplating potential monetization of our proprietary technology in larger markets.

We intend to advance development of our drug candidates 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.

Recent Developments

XCART Technology

On March 1, 2019, we entered into an agreement to acquire the XCART platform technology (the "Transaction") a proximity-based screening platform capable of identifying CAR constructs that can target patient-specific tumor neoantigens, with a demonstrated proof of mechanism in B-cell Non-Hodgkin 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.

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, 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.

In connection with the Transaction, we entered into a Share Purchase Agreement (the "Share Purchase Agreement") pursuant to which we will purchase all of the issued and outstanding shares of capital stock of Hesperix SA, a Swiss corporation ("Hesperix"), as well as additional transaction documents. Concurrent with the Share Purchase Agreement, we also entered into an assignment agreement with OPKO Pharmaceuticals, LLC ("OPKO") (the "OPKO Assignment Agreement") pursuant to which the Company will acquire and accept all of OPKO's right, title and interest in an Intellectual Property License Agreement entered into between the Institute and OPKO related to the XCART technology. In total, we will issue 7.5 million shares of our common stock in the Transaction, including 4.875 million shares to be issued to the shareholders of Hesperix and 2.625 million shares of common stock to be issued in connection with the OPKO Assignment Agreement. The closing of the Transaction is subject to customary closing conditions as well as conditions regarding (i) the Company having adequate financing to fund its future working capital obligations following the closing and (ii) the Company obtaining necessary and appropriate stockholder approvals, evidencing among other matters, approval of the Share Purchase Agreement and the transactions contemplated thereunder, including the issuance of the Transaction Shares (as defined below). Subject to the satisfaction of the closing conditions, the Transaction is expected to close in the first half of 2019.

We intend to pursue development efforts of the XCART technology once the acquisition is consummated and pursue other development efforts around CAR T technology. We also plan to pursue collaborations with immuno-oncology ("I-O") companies in which we would seek to use XBIO-101 in combination with approved or developmental I-O compounds such as checkpoint inhibitors subject to adequate funding.

Risks Related to Our Business

Investing in our common stock involves substantial risk. You should carefully consider all of the information in this prospectus before investing in our common stock, including the risks related to this offering and our common stock, our business and industry, our intellectual property, our financial results, and our need for financing, each as described under the section titled "Risk Factors" and elsewhere in this prospectus.

Corporate Information

We were incorporated under the laws of the State of Nevada in August 2011. Our corporate headquarters and operation facilities are located at 40 Speen Street, Suite 102, Framingham, MA 01701. Our telephone number is (781) 778-7720. We maintain a website at www.xeneticbio.com.

THE OFFERING

Common stock offered by us:	[●] shares
Common stock to be outstanding after this offering (1):	[●] shares
Option to purchase additional shares:	The underwriters have an option within 45 days of the date of this prospectus to purchase up to [●] additional shares of our common stock to cover over-allotments, if any.
The Nasdaq Capital Market Symbol	XBIO
Use of proceeds:	We estimate that the net proceeds from this offering will be approximately $[●] (or approximately $[●] if the underwriters exercise their option to purchase additional shares in full), assuming a public offering price of $[●] per share, after deducting underwriting discounts and commissions and the estimated offering expenses payable by us. We intend to use the net proceeds from the sale of the shares to fund our research, development and clinical programs, including the development of the XCART technology, as described below in the section titled "The Transaction," and for other general corporate purposes. See "Use of Proceeds" on page [●] of this prospectus.
Risk factors:	You should read the "Risk Factors" section beginning on page [●] and other information included in this prospectus for a discussion of factors to consider carefully before deciding to invest in our securities.
Lock-ups:	Our officers and directors and certain holders of our capital stock will enter into lock-ups restricting the transfer of shares of or relating to our capital stock for 180 days after the date of this prospectus.

(1) The number of shares of our Common Stock outstanding immediately after this offering is based on 10,443,889 shares of our common stock outstanding as of March 31, 2019, and excludes:

- 970,000 shares of Common Stock underlying outstanding Series A Preferred Stock, which are convertible into Common Stock on a one-for-one basis;
- 3,608,788 shares of Common Stock underlying outstanding Series B Preferred Stock, which are convertible into Common Stock on a two-for-one basis;
- 509,000 shares of Common Stock issuable upon the exercise of outstanding pre-funded warrants;
- 5,240,427 shares of Common Stock issuable upon the exercise of outstanding warrants;
- 1,833,011 shares of Common Stock issuable upon the exercise of outstanding options;
- 50,000 shares of Common Stock underlying outstanding restricted stock units;
- 97,036 shares of Common Stock issuable in connection with the Common Stock awards; and
- 7,500,000 shares of Common Stock to be issued in connection with the Transaction, including 4,875,000 shares of Common Stock to be issued to the Hesperix Sellers and 2,625,000 shares of Common Stock to be issued in connection with the OPKO Assignment Agreement.

SUMMARY FINANCIAL DATA

The following tables summarize our financial data for the periods presented and should be read together with the sections of this prospectus titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," and our financial statements and related notes thereto appearing elsewhere in this prospectus. The following summary statements of operations data for the years ended December 31, 2018 and 2017 and the three months ended March 31, 2019 and 2018 have been derived from our financial statements and footnotes included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results we expect in the future.

	Year ended December 31,		Three Months ended March 31,	
	2018	2017	2019	2018
Revenue	$ –	$ 7,585,000	$ –	$ –
Cost of research and development revenue	–	(156,119)	–	–
Gross profit	–	7,428,881	–	–
Operating expenses:				
Research and development	(2,883,952)	(4,060,000)	(463,782)	(706,271)
General and administrative	(4,392,375)	(6,937,643)	(863,373)	(1,122,072)
Total operating expense	(7,276,327)	(10,997,643)	(1,327,155)	(1,828,343)
Loss from Operations	(7,276,327)	(3,568,762)	(1,327,155)	(1,828,343)
Other income (expense)	(24,131)	(26,370)	(95)	5,825
Net loss	$ (7,300,458)	$ (3,595,132)	$ (1,327,250)	$ (1,822,518)

The following summary balance sheet data as of March 31, 2019 is presented:

- on an actual basis; and
- on an as adjusted basis to give effect to our sale of shares of common stock in this offering at the assumed offering price of $ per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

The summary as adjusted balance sheet is for informational purposes only and does not purport to indicate balance sheet information as of any future date.

	March 31, 2019	
	Actual	**As Adjusted[1]**
	(Unaudited)	
Balance Sheet data:		
Cash and restricted cash	$ 2,084,643	$
Total assets	16,456,192	
Total liabilities	4,937,664	
Accumulated deficit	(154,560,845)	
Total stockholders' equity	$ 11,518,528	$

(1) Each $1.00 increase (decrease) in the assumed public offering price of $ per share would increase (decrease) the as adjusted amount of cash and cash equivalents, total assets, and total stockholders' equity by approximately $ million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the number of shares we are offering. Each increase (decrease) of 100,000 shares in the number of shares offered by us would increase (decrease) the as adjusted amount of cash and cash equivalents, total assets, and total stockholders' equity by approximately $ million, assuming that the assumed public offering price remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. The as adjusted information discussed above is illustrative only and will be adjusted based on the actual public offering price and other terms of this offering determined at pricing.

RISK FACTORS

Investing in our common stock involves a high degree of risk. Before you invest in our common stock, you should carefully consider the following risks, as well as general economic and business risks, and all of the other information contained in this prospectus. Any of the following risks could harm our business, operating results and financial condition and cause the trading price of our common stock to decline, which would cause you to lose all or part of your investment. When determining whether to invest, you should also refer to the other information contained in this prospectus, including our financial statements and the related notes thereto.

Risks Related to Our Common Stock and This Offering

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

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

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

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

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

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

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

As of March 31, 2019, our executive officers, directors and affiliates beneficially own approximately 66.7% of our outstanding Common Stock. Therefore, these stockholders will have the ability to influence us through their ownership positions. Further, our majority stockholder, PJSC Pharmsynthez ("Pharmsynthez"), has beneficial ownership of approximately 9.3 million shares of Common Stock. These shares represent ownership of approximately 64.8% of our Common Stock as of March 31, 2019. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders, acting together, may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited transaction proposals or offers for our Common Stock that you may believe are in your best interest as one of our stockholders.

We have entered into several agreements with our major stockholders.

We have entered into several agreements with our major stockholders. 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 share of Common Stock and each share of Series B preferred stock is convertible into two shares of Common Stock, subject to certain adjustments, which may cause substantial dilution to our common stockholders. The preferential rights could result in divergent interests between the holders of shares of preferred stock and holders of our Common Stock. In addition, our majority shareholder, Pharmsynthez holds shares consisting of the majority of our Series B Preferred Stock and all of our Series A Preferred Stock. The interests of these preferred holders may differ from the interests of our security holders as a whole.

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

As of March 31, 2019, we had 10,443,889 shares of Common Stock issued and outstanding, excluding:

- 970,000 shares of Common Stock underlying outstanding Series A Preferred Stock, which are convertible into Common Stock on a one-for-one basis;
- 3,608,788 shares of Common Stock underlying outstanding Series B Preferred Stock, which are convertible into Common Stock on a two-for-one basis;
- 509,000 shares of Common Stock issuable upon the exercise of outstanding pre-funded warrants;
- 5,240,427 shares of Common Stock issuable upon the exercise of outstanding warrants;
- 1,833,011 shares of Common Stock issuable upon the exercise of outstanding options;
- 50,000 shares of Common Stock underlying outstanding restricted stock units;
- 97,036 shares of Common Stock issuable in connection with the Common Stock awards; and
- 7,500,000 shares of Common Stock to be issued in connection with the Transaction, including 4,875,000 shares of Common Stock to be issued to the Hesperix Sellers and 2,625,000 shares of Common Stock to be issued in connection with the OPKO Assignment Agreement.

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.

Investors in this offering will experience immediate and substantial dilution in net tangible book value.

The public offering price will be substantially higher than the net tangible book value per share of our outstanding shares of common stock. As a result, investors in this offering will incur immediate dilution of [•] per share, based on the assumed public offering price of [•] per share. Investors in this offering will pay a price per share that substantially exceeds the book value of our assets after subtracting our liabilities. See "Dilution" for a more complete description of how the value of your investment will be diluted upon the completion of this offering.

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.

Our management will have broad discretion as to the use of proceeds from this offering, and we may not use the proceeds effectively.

Our management will have broad discretion in the application of the net proceeds from this offering and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our Common Stock. You will not have the opportunity, as part of your investment decision, to assess whether these proceeds are being used appropriately. Our failure to apply these funds effectively could have a material adverse effect on our business and cause the price of our Common Stock to decline.

We expect that we may need additional capital in the future; however, such capital may not be available to us on reasonable terms, if at all, when or as we require additional funding. If we issue additional shares of our Common Stock or other securities that may be convertible into, or exercisable or exchangeable for, our Common Stock, our existing stockholders would experience further dilution.

Although we expect that we may need additional capital in the future, we cannot be certain that it will be available to us on acceptable terms when required, or at all. Disruptions in the global equity and credit markets may limit our ability to access capital. To the extent that we raise additional funds by issuing equity securities, our shareholders would experience dilution, which may be significant and could cause the market price of our Common Stock to decline significantly. Any debt financing, if available, may restrict our operations. If we are unable to raise additional capital when required or on acceptable terms, we may have to significantly delay, scale back or discontinue certain operations. Any of these events could significantly harm our business and prospects and could cause our stock price to decline.

Risks Related to the Transaction

We cannot assure you that the proposed Transaction will be completed on a timely basis or at all or that the Company will recognize the anticipated benefits of the Transaction.

On March 1, 2019, we entered into an agreement to acquire the novel CAR T platform technology, referred to herein as "XCART," a proximity-based screening platform capable of identifying CAR constructs that can target patient-specific tumor neoantigens, with a demonstrated proof of mechanism in B-cell Non-Hodgkin lymphomas. The XCART technology, developed by the Institute in collaboration with the 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.

There are a number of risks and uncertainties relating to the Transaction. For example, the Transaction may not be completed, or may not be completed in the time frame, on the terms or in the manner currently anticipated and the Company may not recognize the anticipated benefits of the Transaction, as a result of a number of factors, including the following:

- that one or more closing conditions to the Transaction, including certain regulatory approvals, may not be satisfied or waived, on a timely basis or otherwise, that the required approval by the stockholders of the Company may not be obtained, and the Company may not have adequate financing to fund its future working capital obligations following the closing;
- unexpected costs, charges or expenses resulting from the Transaction;
- uncertainty of the expected financial performance of the Company following completion of the Transaction;
- the ability of the Company to implement its business strategy; and
- the occurrence of any event that could give rise to termination of the Transaction.

Our business will substantially depend on the success of XCART.

Our business will substantially depend on the successful consummation of the acquisition of the XCART platform technology and its clinical development, regulatory approval and commercialization. It will require substantial clinical development and regulatory approval efforts before we are permitted to commence its commercialization, if ever. 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 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.

Some of the Company's directors and principal stockholders have interests in the Transaction that may differ from, or are in addition to, those of the Company's other stockholders.

In considering whether to approve the Transaction, the Company's stockholders should recognize that certain of the Company's directors and stockholders have interests in the Transaction that may differ from, or that are in addition to, their interests as stockholders generally. These interests include, among others, (i) Dr. Genkin, a director of the Company, serves as the Executive Chairman of Pharmsynthez, the Company's largest and controlling stockholder with ownership of approximately 51.4% of the Company's issued and outstanding Common Stock as of March 31, 2019, (ii) Mr. Knyazev, a director of the Company, is also a director of Pharmsynthez, (iii) Dr. Curtis Lockshin, an executive officer of the Company, is an officer of a wholly-owned subsidiary of Pharmsynthez, and (iv) Adam Logal, a director of the Company, is the Senior Vice President and Chief Financial Officer of OPKO Health, which owns approximately 3.9% of the Company's issued and outstanding Common Stock and approximately 9.0% of the issued and outstanding stock of Pharmsynthez. These interests may cause some of the interested parties to view the Transaction differently than you may view them as a disinterested stockholder of the Company, and may influence or may have influenced the interested parties in determining to support or approve the Transaction.

The market price of the Company's Common Stock may decline as a result of the Transaction.

The market price of the Company's Common Stock may decline as a result of the Transaction for a number of reasons including:

- the Company may not achieve the perceived benefits of the Transaction as rapidly or to the extent anticipated;
- the effect of the Transaction on the Company's business and prospects is not consistent with the expectations of financial or industry analysts; or
- investors react negatively to the effect Company's business and prospects resulting from the Transaction.

The number of shares of Common Stock that the Sellers, OPKO, and the Institute will receive in the Transaction will not change based on the market price of our Common Stock so the consideration that the Sellers, OPKO, and the Institute will receive at the closing of the Transaction may have a greater or lesser value than the value at the time the Transaction documents were entered into.

The Transaction documents set the number of Transaction Shares of our Common Stock to be issued in the Transaction. Any changes in the market price of our Common Stock before the completion of the Transaction will not affect the number of Transaction Shares issuable pursuant to the Transaction. Therefore, if before the completion of the Transaction the market price of our Common Stock declines from the market price on the date of the Transaction Documents, then paid by the Company in the Transaction may have a consideration with substantially lower value at closing. Conversely, if before the completion of the Transaction the market price of our Common Stock increases from the market price on the date of the Transaction Documents, then paid by the Company in the Transaction may have a consideration with substantially greater value at closing.

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 2018 we focused solely on the development of XBIO-101. We continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we have never been profitable and we may not achieve profitability in the foreseeable future, if at all. Our ability to generate profits in the future will depend on a number of factors, including:

- Funding the costs relating to the research and development, regulatory approval, commercialization and sale and marketing of our drug candidates and technologies;
- 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 March 31, 2019, we had an accumulated deficit of approximately $154.6 million. Substantial doubt exists about our ability to continue as a going concern as a result of anticipated capital needs. We expect to incur additional significant operating losses as we expand our research and development activities and our commercialization, marketing and sales efforts. We may also encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. In addition, because of the numerous risks and uncertainties associated with pharmaceutical product development, including that our current drug candidates may not achieve the clinical endpoints of applicable trials, we are unable to predict the timing or amount of increased expenses, and if or when we will achieve or maintain profitability. If we are unable to generate sufficient revenue from our operations to pay expenses or we are unable to obtain additional financing on commercially reasonable terms, our business, financial condition and results of operations may be materially and adversely affected.

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

We have concluded there is substantial doubt about our ability to continue as a going concern. As described in their audit report, our auditors have included an explanatory paragraph that states that we have incurred recurring losses and negative cash flows from operations since inception and have an accumulated deficit at March 31, 2019 of $154.6 million. These matters raise substantial doubt about our ability to continue as a going concern. Our consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. If we cannot continue as a viable entity, our stockholders may lose some or all of their investment in us.

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

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 March 31, 2019, we had cash and restricted cash of $2.1 million. We expect that we will require additional capital to complete clinical trials, obtain regulatory approval for, and to commercialize, our drug candidates, including our other preclinical drug candidates and our future drug candidates. However, our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings, third-party funding, marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or a combination of these approaches. In any event, we will require additional capital to pursue preclinical and clinical activities, pursue regulatory approval for, and to commercialize, our longer term pipeline drug candidates. Even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic considerations.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our drug candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. Moreover, the terms of any financing may negatively impact the holdings or the rights of our stockholders, and the issuance of additional securities, whether equity or debt, by us or the possibility of such issuance may cause the market price of our shares to decline. The incurrence of indebtedness could result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business.

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

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

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

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

Risks Related to the Discovery and Development of our Pharmaceutical Products

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

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

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

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

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

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

- Severity of the disease under investigation;
- Real or perceived availability of alternative treatments;
- Size and nature of the patient population;
- Eligibility criteria for and design of the trial in question;
- Perceived risks and benefits of the drug candidate under study;
- Proximity and availability of clinical sites for prospective patients;
- Ongoing clinical trials of potentially competitive agents;
- Physicians' and patients' perceptions as to the potential advantages of our drug candidates being studied in relation to available therapies or other products under development;
- Our 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.

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 disagrees with the promotion, marketing or labeling of a product, such regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:

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

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

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

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

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

Even if a potential product displays a favorable efficacy and safety profile in preclinical and clinical studies, market acceptance of the product will not be known until after it is launched. Our efforts to educate the medical community and third-party payors on the benefits of the pharmaceutical products may require 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 or drug candidates or for indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs for drug candidates may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular drug candidate, we may relinquish valuable rights to that drug candidate through strategic collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such drug candidate, or we may allocate internal resources to a drug candidate in a therapeutic area in which it would have been more advantageous to enter into a partnering arrangement. Failure to pursue opportunities with greater commercial potential or relinquishing valuable rights to drug candidates may adversely impact our business, results of operations and prospects.

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

The success of our business depends primarily upon our ability to identify and develop pharmaceutical products. 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, while we may seek orphan drug designation for our drug candidates, we may never receive such designations.

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

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

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

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

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

Furthermore, there have been and continue to be a number of initiatives at the federal and state level that seek to reduce healthcare costs. Most significantly, in March 2010, the Patient Protection and Affordable Health Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, was signed into law, which includes measures that significantly change the way healthcare is financed by both governmental and private insurers. In January 2017, Congress voted to adopt a budget resolution for fiscal year 2017, or the Budget Resolution, that authorizes the implementation of legislation that would repeal portions of the ACA. 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. 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, 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 or our CROs or the clinical investigators fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving any marketing applications. Upon inspection, the FDA may determine that our clinical trials did not comply with GCPs. In addition, our future clinical trials will require a sufficient number of test subjects to evaluate the safety and efficacy of our drug candidates. Accordingly, if our CROs or clinical investigators fail to comply with these regulations or fail to recruit a sufficient number of patients, we may be required to repeat such clinical trials, which would delay the regulatory approval process.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We have no manufacturing, sales, marketing or distribution capabilities, and we may have to invest 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 underlying the units.

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

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

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

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

We employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. 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. Although we did not record any such charges during 2018, we are required to perform periodic impairment reviews of those assets at least annually. The carrying value of goodwill on our balance sheet that is subject to impairment reviews was approximately $3.3 million at December 31, 2018 and December 31, 2017 and the carrying value of our indefinite-lived assets was $9.2 million at December 31, 2018 and December 31, 2017. To the extent future reviews conclude that the expected future cash flows generated from our business activities are not sufficient to recover the carrying value of these assets, we will be required to measure and record an impairment charge to write-down these assets to their realizable values and those impairment charges could be equal to the entire carrying value.

We completed our last review during the fourth quarter of 2018 and determined that goodwill and indefinite-lived intangible assets were not impaired as of December 31, 2018. However, there can be no assurance that upon completion of subsequent reviews a material impairment charge will not be recorded. If future periodic reviews determine that our assets are impaired and a write-down is required, it will adversely impact our operating results.

In addition, we recorded non-cash charges of approximately $1.4 million and $1.8 million for share-based expense during the years ended December 31, 2018 and 2017, respectively. In the future, this amount could fluctuate materially as the Company expects to continue to issue share-based payments awards.

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

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

We 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.

On December 22, 2017, the TCJA, which significantly reforms the Internal Revenue Code of 1986, as amended (the “Code”), was signed into law. The TCJA, among other things, includes changes to U.S. federal tax rates, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitations of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitations of the deduction for net operating losses (“NOLs”) to 80% of current year taxable income and elimination of NOL carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, modifying or repealing many business deductions and credits and putting into effect the migration from a “worldwide” system of taxation to a territorial system. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the new federal tax law is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will adjust their policies in response to the newly enacted federal tax law. The impact of this tax reform on holders of our Common Stock is uncertain and could be adverse.

Due to the potential for changes to tax laws and regulations or changes to the interpretation thereof (including regulations and interpretations pertaining to the TCJA), 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 key employees, consultants and advisors and to attract, retain and motivate qualified personnel.

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

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

As of March 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.

CAUTIONARY STATEMENT CONCERNING FORWARD-LOOKING INFORMATION

This Prospectus contains various "forward-looking statements." Forward-looking statements relate to expectations, beliefs, projections, future plans and strategies, anticipated events or trends and similar expressions concerning matters that are not historical facts. 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. All forward-looking statements may be impacted by a number of risks and uncertainties. These forward-looking statements include statements concerning our plans to develop our proposed drug candidate; 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 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 CAR T technology; and the risk that the Transaction may not be completed on the terms or in the timeframe expected by the Company or at all.

The forward-looking statements in this Prospectus are based on our beliefs, assumptions and expectations of our future performance, taking into account all information currently available to us. These beliefs, assumptions and expectations are subject to risks and uncertainties and can change as a result of many possible events or factors, not all of which are known to us. If a change occurs, our business, financial condition, liquidity and results of operations may vary materially from those expressed in our forward-looking statements. You should carefully consider these risks before you make an investment decision with respect to our securities, along with the following factors that could cause actual results to vary from our forward-looking statements:

- our need to raise additional working capital in the very near term for the purpose of developing products and technologies 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 the acquisition of the CAR T technology;
- product development and commercialization risks, including our ability to successfully develop the CAR T technology;
- our ability to successfully commercialize our current and future drug candidates;
- our ability to achieve milestone and other payments associated with our co-development collaborations and strategic arrangements;
- the impact of new technologies on our drug candidates and our competition;
- changes in laws or regulations of governmental agencies;
- interruptions or cancellation of existing contracts;
- impact of competitive products and pricing;
- product demand and market acceptance and risks;
- the presence of competitors with greater financial resources;
- continued availability of supplies or materials used in manufacturing at the current prices;
- the ability of management to execute plans and motivate personnel in the execution of those plans;
- our ability to attract and retain key personnel;
- adverse publicity related to our products or the Company itself;
- adverse claims relating to our intellectual property;
- the adoption of new, or changes in, accounting principles;
- the costs inherent with complying with statutes and regulations applicable to public reporting companies, such as the Sarbanes-Oxley Act of 2002;
- other new lines of business that the Company may enter in the future; and
- other factors set forth in the Risk Factors section of this Prospectus and in subsequent filings we make with the Securities and Exchange Commission.

We cannot guarantee future results, levels of activity, performance or achievements. You should not place undue reliance on forward-looking statements, which apply only as of the date of this Prospectus. We do not intend and disclaim any duty or obligation to update or revise any industry information or forward-looking statements set forth in this Registration Statement to reflect new information, future events or otherwise, except as required under the United States federal securities laws.

USE OF PROCEEDS

We estimate the net proceeds to us from the sale of [●] shares of Common Stock in this offering will be approximately $[●] million after deducting underwriting discounts and commissions and estimated offering expenses payable by us, assuming the issuance and sale of [●] shares of our Common Stock at the assumed public offering price of $[●] . If the option to purchase additional shares is exercised in full, we estimate that our net proceeds will be approximately $[●] million.

We intend to use the net proceeds from the sale of the shares to fund research, development and clinical programs, including the development of the XCART technology, as described below in the section titled “The Transaction,” and for other general corporate purposes. The amounts and timing of our use of proceeds will vary depending on a number of factors, including the amount of cash generated or used by our operations. As a result, we will retain broad discretion in the allocation of the net proceeds of this offering. In addition, while we have not entered into any agreements, commitments or understandings relating to any significant transaction as of the date of this prospectus supplement, we may use a portion of the net proceeds to pursue acquisitions, joint ventures and other strategic transactions.

MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Market Information

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

Holders of Record

As of May 13, 2019, there were 409 holders of record of our Common Stock.

DIVIDEND POLICY

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.

CAPITALIZATION

The following table sets forth our cash and cash equivalents and capitalization as of March 31, 2019:

- on an actual basis; and
- on an as adjusted basis to give effect to our sale of shares of Common Stock in this offering at an assumed public offering price of $[•] per share, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Our capitalization following the closing of this offering will be adjusted based on the actual public offering price and other terms of this offering determined at pricing. You should read this information together with our financial statements and the related notes thereto included elsewhere in this prospectus and the information set forth under the headings "Summary Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this prospectus.

	As of March 31, 2019	
	Actual	As Adjusted
	(in thousands, except share and per share data)	
Cash and restricted cash	$ 2,084,643	$
Current liabilities	2,006,027	
Long-term liabilities	2,931,637	
Stockholders' equity:		
Preferred stock, 10,000,000 shares authorized		
Series B, $0.001 par value: 1,804,394 shares issued and outstanding, actual; _____ shares issued and outstanding, as adjusted	1,804	
Series A, $0.001 par value: 970,000 shares issued and outstanding, actual; _____shares issued and outstanding, as adjusted	970	
Common stock, $0.001 par value; 45,454,546 shares authorized, 10,443,889 shares issued and outstanding, actual; _____ shares authorized, _____ shares issued and outstanding, as adjusted	10,766	
Additional paid-in capital	171,093,279	
Accumulated deficit	(154,560,845)	
Accumulated other comprehensive income	253,734	
Treasury stock	(5,281,180)	
Total stockholders' equity	$ 11,518,528	$
Total capitalization	$ 14,450,165	$

Each $1.00 increase (decrease) in the assumed public offering price of $ per share would increase (decrease) the as adjusted amount of cash and cash equivalents, additional paid-in capital, total stockholders' equity (deficit) and total capitalization by approximately $ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the number of shares we are offering. Each increase (decrease) of 100,000 shares in the number of shares we are offering would increase (decrease) the as adjusted amount of cash and cash equivalents, additional paid-in capital, total stockholders' equity and total capitalization by approximately $ million, assuming that the assumed public offering price remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. The as adjusted information discussed above is illustrative only and will be adjusted based on the actual public offering price and other terms of this offering determined at pricing.

(1) The number of shares of our Common Stock outstanding immediately after this offering is based on 10,443,889 shares of our Common Stock outstanding as of March 31, 2019, and excludes:

- 970,000 shares of Common Stock underlying outstanding Series A Preferred Stock, which are convertible into Common Stock on a one-for-one basis;

- 3,608,788 shares of Common Stock underlying outstanding Series B Preferred Stock, which are convertible into Common Stock on a two-for-one basis;
- 509,000 shares of Common Stock issuable upon the exercise of outstanding pre-funded warrants;
- 5,240,427 shares of Common Stock issuable upon the exercise of outstanding warrants;
- 1,833,011 shares of Common Stock issuable upon the exercise of outstanding options;
- 50,000 shares of Common Stock underlying outstanding restricted stock units;
- 97,036 shares of Common Stock issuable in connection with the Common Stock awards; and
- 7,500,000 shares of Common Stock to be issued in connection with the Transaction, including 4,875,000 shares of Common Stock to be issued to the Hesperix Sellers and 2,625,000 shares of Common Stock to be issued in connection with the OPKO Assignment Agreement.

DILUTION

If you invest in our Common Stock, your interest will be diluted immediately to the extent of the difference between the offering price per share of our Common Stock and the as adjusted net tangible book value per share of our Common Stock immediately after this offering.

As of March 31, 2019, our historical net tangible book value was $1.9 million or $0.18 per share of common stock. Historical net tangible book value per share represents the amount of our total tangible assets less total liabilities, divided by 10,443,889, the number of shares of common stock outstanding on March 31, 2019.

After giving effect to the sale of shares of our common stock in this offering at the assumed offering price of $ per share, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, our net tangible book value as of March 31, 2019 would have been $ million, or $ per share. This amount represents an immediate increase in net tangible book value of $ per share to our existing stockholders and an immediate dilution in net tangible book value of approximately $ per share to new investors purchasing shares of our common stock in this offering. We determine dilution by subtracting the net tangible book value per share after the offering from the amount of cash that a new investor paid for a share of common stock.

The following table illustrates this dilution on a per share basis:

Assumed offering price per share		$
Historical net tangible book value per share as of March 31, 2019	$ 0.18	
Increase in net tangible book value per share attributable to new investors		
Net tangible book value per share after the offering		
Dilution per share to new investors		$

Each $1.00 increase (decrease) in the assumed public offering price of $ per share would increase (decrease) our net tangible book value after this offering by approximately $ million, or approximately $ per share, and increase (decrease) the dilution per share to new investors by approximately $ per share, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the number of shares we are offering. An increase (decrease) of 100,000 shares in the number of shares offered by us would increase (decrease) our net tangible book value after this offering by approximately $ million, or $ per share, and increase (decrease) the dilution per share to new investors by approximately $ per share, assuming that the assumed public offering price remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. The information discussed above is illustrative only and will adjust based on the actual public offering price and other terms of this offering determined at pricing.

If the underwriters exercise their option to purchase additional shares in full, the net tangible book value per share after giving effect to the offering would be $ per share. This represents an immediate increase in as adjusted net tangible book value of $ per share to existing stockholders and an immediate dilution in net tangible book value of $ per share to new investors purchasing shares of our common stock in this offering.

The following table sets forth as of March 31, 2019, on the as adjusted basis described above, the differences between the number of shares of common stock purchased from us, the total consideration paid and the weighted average price per share paid by existing stockholders and by investors purchasing shares of our common stock in this offering, after deducting the estimated underwriting discounts and commissions and estimated offering expenses, at an assumed public offering price of $ per share:

	Shares Purchased		Total Consideration		Weighted Average
	Number	Percent	Amount	Percent	Price per Share
Existing stockholders	10,443,889	%	$ 171,104,045(1)	%	$ 16.38
New investors					
Total		%	$	%	

(1) Represents:

Common Stock – par value	$ 10,766
Additional paid-in capital	171,093,279
	$ 171,104,045

THE TRANSACTION

Overview of the Transaction

On March 4, 2019, Xenetic announced its agreement to the XCART technology, a proximity-based screening platform capable of identifying CAR constructs that can target patient-specific tumor neoantigens, with a demonstrated proof of mechanism in B-cell non-Hodgkin lymphomas. The XCART technology, developed by the Institute in collaboration with 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.

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, 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. Xenetic's clinical development program will seek to confirm the early preclinical results, and to demonstrate a more attractive safety profile than existing therapies.

The Transaction Documents

A summary description of the Transaction Documents and the transactions contemplated thereby is set forth below. Subject to the satisfaction of the closing conditions, the Transaction is expected to close in the first half of 2019.

Share Purchase Agreement

On March 1, 2019 (the "Signing Date"), the Company entered into the Share Purchase Agreement with Hesperix, the Sellers and the Sellers' Representative, pursuant to which the Company will purchase from Sellers all of the issued and outstanding shares of capital stock of Hesperix.

Under the terms of the Share Purchase Agreement, the Company will issue to Sellers an aggregate of Four Million Eight Hundred Seventy-Five Thousand (4,875,000) shares of Common Stock (the "Hesperix Transaction Shares"), regardless of the trading price per share of the Common Stock at the time of the closing.

The closing of the Hesperix Acquisition is subject to customary closing conditions as well as conditions regarding (i) the Company having adequate financing to fund future working capital obligations of the Company following the closing and, (ii) the Company obtaining necessary and appropriate stockholder approvals, evidencing among other matters, approval of the Transaction and the issuance of the Transaction Shares. Subject to the satisfaction of the closing conditions, the Transaction is expected to close in the first half of 2019.

Hesperix Assignment Agreement

On the Signing Date and in connection with the Transaction, Hesperix entered into an assignment agreement (the "Hesperix Assignment Agreement") with the 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 absence of the Hesperix Assignment Agreement, the manufacture, use, offer for sale, sale, or importation of such product would infringe a valid claim of an issued patent or a valid claim of a pending application, if such were issued. Upon completion of the Hesperix Acquisition, the Company will assume the rights and obligations under the Hesperix Assignment Agreement.

OPKO Assignment Agreement and License Agreement

On the Signing Date, the Company entered into the OPKO Assignment Agreement with OPKO, 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 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 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 will issue to OPKO One Million Nine Hundred Sixty-Eight Thousand Seven Hundred Fifty (1,968,750) shares of Common Stock (the "OPKO Transaction Shares") and to the Institute Six Hundred Fifty-Six Thousand Two Hundred Fifty (656,250) shares of Common Stock (the "Institute Transaction Shares," and along with the Hesperix Transaction Shares and the OPKO Transaction Shares, the "Transaction Shares") regardless of the trading price per share of the Company's Common Stock at the time of the closing.

Reasons for the Transaction

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, which the Company believes has the potential to drive significant value for shareholders. 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 the Company's current strategy of focusing on research addressing unmet needs in oncology. The Company's 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.

We believe that our development efforts with XCART should benefit from the fact that the approvals of Kymriah™ and Yescarta™ have validated CAR T as a clinical therapeutic option. As a result, there are a significant number of companies advancing CAR T research, and the field is attracting large amounts of capital. Given the variety and, often, complementary nature of technical and clinical approaches under investigation, the Company also believes that early successes in development of XCART should generate significant collaboration potential.

Anticipated Accounting Treatment

The Transaction is expected to be treated as an asset acquisition by the Company. To determine the accounting for this transaction under United States (U.S.) generally accepted accounting principles (GAAP), a company must assess whether an integrated set of assets and activities should be accounted for as an acquisition of a business or an asset acquisition. Substantially all of the fair value is included in in-process research and development and no substantive processes are being acquired. As such, the Transaction is expected to be treated as an asset acquisition. Asset acquisitions are to be accounted for by allocating costs, including transaction costs, of the acquisition to the acquired assets based on their relative fair value basis.

BUSINESS

Overview

We are a clinical stage biopharmaceutical company focused on the discovery, research and development of next-generation biological drugs and novel oncology therapeutics. We have an extensive patent portfolio of over 170 issued patents in the U.S. and worldwide, covering various aspects of our PolyXen™ platform technology and advanced polymer conjugate technologies, as well as our proprietary biologic drugs and novel oncology drug candidates. We believe our portfolio positions us well for strategic partnership and commercialization opportunities. Our objective is to leverage our portfolio to maximize opportunities to out-license assets from our portfolio in order to generate working capital to both build long-term stockholder value and provide us with the funding necessary for clinical development of our oncology drug candidates through market launch.

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

Our most advanced investigational drug candidate is oncology therapeutic XBIO-101 (sodium cridanimod) for the treatment of progestin resistant endometrial cancer. We have exclusive rights to develop and commercialize XBIO-101 worldwide, except for specified countries in the Commonwealth of Independent States ("CIS"). XBIO-101 has been granted orphan drug designation by the U.S. Food and Drug Administration ("FDA") for the potential treatment of progesterone receptor negative ("PrR-") endometrial cancer in conjunction with progesterone therapy. We commenced a Phase II trial for XBIO-101 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.

Our lead proprietary technology is PolyXen™, 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. 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. Although we hold a broad patent portfolio, because of capital constraints the focus of our internal development efforts in 2018 was limited to research and development of our primary product candidate XBIO-101.

We were incorporated under the laws of the State of Nevada in August 2011. We, directly or indirectly, through our wholly-owned subsidiary, Xenetic 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 OncoHist, PolyXen, ErepoXen, and ImuXen.

Our Strategy

The acquisition of the XCART platform technology is expected to close in the first half of 2019, subject to the approvals and other conditions discussed in this Registration Statement. We plan to initially apply the XCART technology to develop cell-based therapeutics for the treatment of B-cell Lymphomas. 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 anticipate that our primary focus once the Transaction is completed will be on advancing this technology through regulatory approval and commercialization.

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

We intend to pursue orphan drug designations 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 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 the Company in the form of access to partner-generated clinical data, which is informative when contemplating potential monetization of our proprietary technology in larger markets.

We intend to advance development of our drug candidates 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.

We intend to pursue development efforts of the XCART technology once the acquisition is consummated and pursue other development efforts around CAR T technology. We also plan to pursue collaborations with immuno-oncology ("I-O") companies in which we would seek to use XBIO-101 in combination with approved or developmental I-O compounds such as checkpoint inhibitors subject to adequate funding.

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

We commenced the Phase II trial 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. We are in the process of identifying development paths for XBIO-101, particularly those that can efficiently leverage our existing human data and regulatory status to extend development into I-O settings.

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 with our biotechnology and pharmaceutical collaborators, with the goal of creating what we believe will be the next generation of biologic drugs and therapeutics. While we primarily focus on researching and developing oncology drugs, we also have ownership and other economic interests in drugs being developed by our collaborators to treat other conditions. Our patent portfolio spans four core proprietary technologies including two platforms, small molecules and biologics covering multiple drug candidates and indications including XBIO-101, PolyXen, OncoHist and ImuXen. We have primarily been focused on the advancement of XBIO-101 through clinical trials. We have not been actively pursuing development efforts for PolyXen, OncoHist and ImuXen due to capital restraints. We anticipate that the focus of our future internal development efforts will be limited to research and development of our XCART technology as well as potential I-O applications for our product candidate XBIO-101.

XBIO-101	A small molecule therapeutic with the potential to confer sensitivity to hormone therapeutics upon cancer cells that are otherwise insensitive to such treatments. XBIO-101 (sodium cridanimod) belongs to a class of low-molecular weight synthetic interferon inducers. In addition to its immunomodulatory properties, XBIO-101 has been shown to increase levels of progesterone receptor, or PrR, expression in tumor tissue of patients who are PrR-, and thus may restore sensitivity of non-responsive endometrial cancers to hormonal (e.g., progestin) therapy. Based on preclinical observations, XBIO-101 may also be therapeutically relevant in other hormone-therapy resistant cancers, such as triple-negative breast cancer. XBIO-101 has been granted an orphan drug designation by the FDA for the potential treatment of progesterone receptor negative endometrial cancer in conjunction with progesterone therapy. Sodium cridanimod has been the subject of numerous nonclinical studies as well as 21 foreign controlled clinical trials totaling 750 subjects, which supported marketing authorizations in ex-Soviet territories, as well as enablement of our active US IND. We believe that XBIO-101 may also have utility, alone or in combination, in immuno-oncology approaches. The Company is therefore seeking to advance the compound in collaboration with I-O focused partners.
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 2018 was limited to research and development of XBIO-101 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 XBIO-101 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 Russian pharmaceutical company and presently our majority stockholder;
- Serum Institute of India Limited ("Serum Institute"), one of the world's largest vaccine manufacturers and one of India's largest biotech companies, as well as a beneficial owner of over 5% of our Common Stock; and
- Takeda Pharmaceuticals Co. Ltd (formerly Shire plc) ("Takeda"), a global biopharmaceutical leader.

Accordingly, in addition to pursuing the development of our pipeline of next-generation bio-therapeutics and novel oncology drugs, we also have significant interests in drug candidates being developed by our collaborators to treat other conditions. We may collect milestone payments and royalties pursuant to these collaborations to the extent that these drugs are successfully developed and marketed. However, other than potential 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 with our biotechnology and pharmaceutical collaborators. The following discussion summarizes key information regarding our current drug candidates, organized by our internal programs and our collaborators' programs:

XBIO-101

XBIO-101 is our most advanced internal candidate with an orphan drug designation from the FDA for the potential treatment of progesterone receptor negative endometrial cancer in conjunction with progesterone therapy. An 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 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, we were pursuing the use of XBIO-101 for the treatment of endometrial cancer.

Our decision to investigate XBIO-101 for the treatment of endometrial cancer was based in part on the history of sodium cridanimod in preclinical and clinical research conducted by others, including prior clinical trials conducted and completed in Russia that assessed the efficacy and safety of sodium cridanimod. Sodium cridanimod has been authorized for medicinal use in the Russian Federation for 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 the Phase II trial under the IND in 2017, with the first patient dosed in October 2017. We closed patient enrollment of the trial in March 2019 as a result of slower than expected progress on the trial resulting from patient enrollment and retention challenges. We are in the process of identifying development paths for XBIO-101, particularly those that can efficiently leverage our existing human data and regulatory status to extend development into immune-oncology settings.

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 terminated our clinical development efforts of ErepoXen and continue to seek 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. Each cohort represents an increased dose of ErepoXen that is given on a repeat schedule until therapeutic levels of hemoglobin are achieved. In our study there were no serious Treatment Emergent Adverse Events ("TEAE") related to ErepoXen in either cohort 1 or 2. There was one serious TEAE in cohort 3 judged to be possibly related, but not unexpected given the safety profile of other Erythropoietin Stimulating Agents.

In addition, Serum Institute finished Phase I/II clinical trials in India of ErepoXen for in-center-dialysis patients. Serum Institute has submitted a clinical trial application to conduct a Phase II(b)/III clinical trial for PSA-EPO in India.

SynBio received regulatory approval to commence ErepoXen Phase II(b)/III human clinical trials in Russia, is currently recruiting patients and 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

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"). Currently, all our development efforts regarding OncoHist remain on hold due to capital constraints. We would expect to file an IND application for OncoHist for AML once we are able to raise sufficient capital and reactivate our development efforts.

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

We have 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 our focus on other product candidates and limited capital resources.

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 our 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.

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

We are in the process of identifying development paths for XBIO-101, particularly those that can efficiently leverage our existing human data and regulatory status to extend development into immuno-oncology settings. We are seeking partners for conducting preclinical and Phase I – Phase II studies, such as human clinical dose ranging and biomarker studies of XBIO-101, alone and in combination with I-O therapeutics including checkpoint inhibitors.

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

Significant Co-Development Collaborations and Strategic Arrangements

Takeda Pharmaceuticals Co. Ltd. ("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 (collectively "Baxalta"), wholly-owned subsidiaries of Takeda, related to the development of a novel series of polysialylated blood coagulation factors. This collaboration with Takeda relies on the Company's PolyXen technology to conjugate PSA to therapeutic blood-clotting factors, with the goal of improving the pharmacokinetic profile and extending the active life of these biologic molecules. The agreement grants 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.

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. To our knowledge, there were no drug-related adverse events, serious adverse events, or rFVIII inhibitors reported to date. Though the trial's pre-defined once-weekly dosing criterion was not met, we intend to continue to explore the potential for future collaborations with Takeda and Takeda has commenced a new, undisclosed project under the agreement.

In October 2017, we entered into a right to sublicense agreement (the "Sublicense Agreement") with Baxalta. Pursuant to the sublicense agreement, we granted to Baxalta the right to grant a nonexclusive sublicense to licensed patents in connection with products related to the treatment of blood and bleeding disorders ("Covered Products"). Pursuant to the sublicense agreement, Baxalta paid us a one-time payment of seven million five hundred thousand dollars ($7,500,000) in November 2017 and agreed to pay us single digit royalty payments based upon net sales of the Covered Products throughout the term, each of which is conditioned upon the performance of the sublicense contemplated by the sublicense agreement. No royalties have been received to date.

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, 2018 and 2017, we have recognized no supply service revenues in connection with the Co-Development Agreement. Among other provisions, the parties may terminate the Co-Development Agreement in relation to a particular product upon 30 days' written notice, if such party, in its reasonable opinion, believes that a third-party IP right exists, which would have a material effect on the research and/or development of the relevant product. Further, the parties may terminate the Co-Development Agreement if the other party is in material breach of the Co-Development Agreement and, in the case of a breach capable of remedy, the breach is not remedied within 90 days of receiving notice specifying the breach and requiring its remedy, or if the other party becomes insolvent. The parties also may terminate the Co-Development Agreement by immediate written notice to the other party in relation to a specific product such if product does not meet the relevant success criteria for the product.

In furtherance of our co-development clinical objectives, on December 31, 2014, we granted SynBio a warrant to purchase 204,394 shares of our Common Stock that contain vesting triggers based on the achievement by SynBio of certain clinical development objectives within specific timeframes (the "SynBio 2014 Warrant"). Simultaneously with the issuance of the SynBio 2014 Warrant, we granted additional warrants to purchase 9,697 aggregate new shares of our Common Stock to SynBio and Pharmsynthez non-director designees under the same terms and conditions of the SynBio 2014 Warrant. No warrants were exercised during the years ended December 31, 2018 and 2017. The vesting criteria for these warrants were not met and, as a result, the warrants expired during the year ended December 31, 2018.

In 2017, SynBio became a wholly-owned subsidiary of Pharmsynthez and all ownership percentages previously 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.

Serum Institute

In August 2011, we entered into a collaborative research and development agreement (the "Serum Agreement") with Serum Institute amending and restating a series of earlier agreements and providing Serum Institute an exclusive license to use our PolyXen technology to research and develop one potential commercial product, PSA-EPO. Serum Institute is responsible for conducting all preclinical and clinical trials required to achieve regulatory approvals within territories outside of certain predetermined territories assigned to us, which include the U.S., the European Economic Area, and Japan, among other territories, at Serum Institute's own expense. Royalty payments are payable by Serum Institute to us for net sales to certain customers in the Serum Institute sales territory. Royalty payments are payable by us to Serum Institute for net sales received by us over the term of the license. No royalty, revenue or expense was recognized by us related to the Serum Institute arrangement during the years ended December 31, 2018 and 2017 and the three months ended March 31, 2019. There are no milestone or other research-related payments due under the Serum Agreement.

Through March 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 96,970 shares of our Common Stock that contain vesting triggers based on the achievement by Serum Institute of certain clinical development objectives within specific timeframes ("Serum 2014 Warrant"). Simultaneously with the issuance of the Serum 2014 Warrant, we issued additional warrants to purchase an aggregate of 4,852 shares of our Common Stock to Serum Institute non-director designees under the same terms and conditions of the Serum 2014 Warrant. The Serum 2014 Warrant expires on December 30, 2019 and no warrants were exercised during any of the years ended December 31, 2018 and 2017 and the three months ended March 31, 2019.

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, with a share ownership of approximately [●]% of our total issued Common Stock as of May [●], 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 2022 with the majority of the existing issued patents expiring between 2025 and 2030.

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

As of February 28, 2019, 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 filed patent applications, and plan to file additional patent applications, covering various aspects of our PolyXen platform technology covering polysialylation and advanced polymer conjugate technologies, 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 produces clinical materials for use in the development of drug candidates involving our PolyXen technology. We are currently dependent on Kevelt for clinical materials with respect to our XBIO-101 research program.

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 I***: 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 II***: 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 III***: 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

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.

Environmental Regulation

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

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

Research and Development Expenses

Research and development activities include personnel costs, research supplies, clinical and preclinical study costs. Such expenses related to the research and development of our drug candidates totaled $0.5 million for the three months ended March 31, 2019 and $0.7 million for the three months ended March 31, 2018.

Research and development activities include personnel costs, research supplies, clinical and preclinical study costs. Such expenses related to the research and development of our drug candidates totaled $2.9 million for the year ended December 31, 2018 and $4.1 million for the year ended December 31, 2017.

Employees

At March 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 are subject to certain statutory and contractual obligations in instances where we terminate U.K.-based employees. These obligations, which are ordinary and customary in the U.K., generally range from one to 12 months of wages for terminated employees and would not be expected to represent a material adverse effect to us.

To complement our own professional staff, we utilize specialists in regulatory affairs, pharmacovigilance, process engineering, manufacturing, quality assurance, 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

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

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

A number of additional therapeutic classes are in development worldwide, including but not limited to antibodies, antibody-drug conjugates, and immunotherapies. Additionally, there are a number of targeted agents including PARP inhibitors and other agents that target the PI3K/Akt/mTOR pathway and other kinase inhibitors. The aforementioned therapeutics and therapeutic classes may be used either alone or in combination.

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.

Properties

We occupied a facility consisting of approximately 4,000 square feet in the Ledgemont Technology Center in Lexington, Massachusetts. The premises were divided into approximately 50% laboratory and 50% office space and were leased by our subsidiary, Xenetic Bioscience, Incorporated. The lease provided for an initial term of 61 months which commenced in January 2014 and expired on January 31, 2019. Commencing February 1, 2019, 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 was extended for an additional two years through November 30, 2019. We believe that this space is adequate for our current needs and that if additional space is required, it can be obtained at commercially reasonable terms either within its current space or nearby.

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 March 31, 2019, that, in the opinion of management, might have a material adverse effect on our financial position, results of operations or cash flows.

Corporate Information

We were incorporated under the laws of the State of Nevada in August 2011. Our corporate headquarters and operation facilities are located at 40 Speen Street, Suite 102, Framingham, MA 01701. Our telephone number is (781) 778-7720. We maintain a website at www.xeneticbio.com.

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 Registration Statement on Form 10-K. Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K and amendments to those reports are available, free of charge, on or through our website as soon as practicable after we electronically file such forms, or furnish them to, the SEC. The public may read and copy any materials we file with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Washington, D.C. 20549. Information on the operations of the Public Reference Room can be obtained by calling 1-800-SEC-0330. The SEC maintains an internet site that contains reports, proxy and information statements and other information regarding our filings at www.sec.gov.

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

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

Management's Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion and analysis in conjunction with our consolidated financial statements and the notes to those financial statements included elsewhere in this Prospectus. This discussion contains forward-looking statements based upon current expectations that involve risks and uncertainties. See "Cautionary Statement Regarding Forward-Looking Information." Our actual results may differ materially from those contained in or implied by any forward-looking statements.

BUSINESS OVERVIEW

Our Phase II trial for our novel oncology product, XBIO-101, commenced patient dosing in October 2017. We closed patient enrollment of the trial in March 2019 as a result of slower than expected progress on the trial resulting from patient enrollment and retention challenges.

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. Although we hold a broad patent portfolio, the focus of our internal development efforts during 2018 was limited to research and development of XBIO-101 due to capital constraints.

On March 1, 2019, the Company entered into an agreement to acquire XCART, a proximity-based screening platform capable of identifying CAR constructs that can target patient-specific tumor neoantigens, with a demonstrated proof of mechanism in B-cell Non-Hodgkin lymphomas. The XCART technology, developed by the Institute in collaboration with the 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. The closing of the Transaction is subject to customary closing conditions as well as conditions regarding (i) the Company having adequate financing to fund its future working capital obligations following the closing and (ii) the Company obtaining necessary and appropriate stockholder approvals, evidencing among other matters, approval of the Share Purchase Agreement and the transactions contemplated thereunder, including the issuance of the transaction shares. Subject to the satisfaction of the closing conditions, the transaction is expected to close in the first half of 2019.

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 and continue to be reported in accordance with ASC 605. 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 the consolidated financial statements. Under ASC 605, we recognized revenue when all of the following criteria were met: (i) persuasive evidence of an arrangement existed; (ii) delivery had occurred or services had been rendered; (iii) the seller's price to the buyer was fixed or determinable; and (iv) collectability was reasonably assured.

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 us 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, sublicense 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.

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 we will collect the consideration we are entitled to in exchange for the goods or services we transfer 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).

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 our actual volatility and of comparable public companies over the expected term of the option. The expected terms represent the time that options are expected to be outstanding. We account for forfeitures as they occur and not at the time of grant. 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. 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.

The fair value of Common Stock awards issued in exchange for services provided by non-employees is generally determined by using the fair value of the services provided, as this provides the most reliable measure of the fair value of the awards. Share-based 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, which requires the input of subjective assumptions and judgments, including estimating the expected term of the awards and the share price volatility, at each reporting period until the measurement date is reached. The expected term is deemed to be the contractual life of the warrant and we determine the expected volatility based on a weighted-average of the historical volatility of a peer group of comparable publicly traded companies with drug candidates in similar stages of development to our drug candidates in conjunction with our historical volatility.

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

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

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

Goodwill and Indefinite-lived Intangible Assets

Goodwill

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

We determine our reporting unit by identifying the components of our operating segment with similar economic characteristics based on quantitative and qualitative factors that have discrete financial information available. We determined that we have one reporting unit as of October 1, 2018 and 2017, the dates of our annual impairment reviews. Based on our annual impairment reviews, we used the quantitative method and determined no adjustment to the carrying value of goodwill would be necessary as the fair value of our reporting unit exceeded its respective carrying value as of October 1, 2018 and 2017, respectively. There can be no assurance that future events will not result in an impairment of goodwill.

Indefinite-lived Intangible Assets

Our indefinite-lived intangible assets consist of acquired in-process research and development (“IPR&D”). IPR&D intangible assets are considered indefinite-lived intangible assets until completion or abandonment of the associated research and development efforts. IPR&D is not amortized but is reviewed for impairment annually as of October 1, or when events or changes in the business environment indicate the carrying value may be impaired. If the fair value of the intangible asset is less than the carrying amount, we perform a quantitative test to determine the fair value. The impairment loss, if any, is measured as the excess of the carrying value of the intangible asset over its fair value. We also have the option to first assess qualitative factors to determine whether the existence of events or circumstances leads us to determine that it is more likely than not (that is, a likelihood of more than 50%) that our indefinite-lived intangible asset is impaired. If we choose to first assess qualitative factors and it is determined that it is not more likely than not our indefinite-lived intangible asset is impaired, we are not required to take further action to test for impairment. We also have the option to bypass the qualitative assessment and perform only the quantitative impairment test, which we may choose to do in some periods but not in others. As the option to perform the qualitative assessment is not a permanent election, we reassess this option during each annual impairment review. During 2018 and 2017, we used the quantitative method and determined the fair value of the indefinite-lived intangible asset exceeded its carrying value as of October 1, 2018 and 2017.

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

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

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

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

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

We did not record an impairment charge as a result of our goodwill or indefinite-lived intangible asset impairment tests in 2018 or 2017. We will continue to closely monitor the performance of our indefinite-lived intangible asset and reporting unit. If the business experiences adverse changes in our key assumptions and judgments, we will perform an interim goodwill and/or indefinite-lived intangible asset impairment analysis. There can be no assurance that future events will not result in an impairment of our goodwill or indefinite-lived intangible asset. As a result of the going concern uncertainty discussed under *Liquidity and Capital Resources* below, the recoverability and classification of the Company's intangible assets and goodwill could be adversely affected.

Results of Operations

Comparison of Three Months ended March 31, 2019 to Three Months ended March 31, 2018

The comparison of our historical results of operations for the fiscal quarter ended March 31, 2019 to the fiscal quarter ended March 31, 2018 is as follows:

Description	Quarter Ended March 31, 2019	Quarter Ended March 31, 2018	Increase (Decrease)	Percentage Change
Research and development expenses	$ (463,782)	$ (706,271)	$ (242,489)	(34.3)
General and administrative expenses	(863,373)	(1,122,072)	(258,699)	(23.1)
Loss from operations	(1,327,155)	(1,828,343)	(501,188)	(27.4)
Other income (expense):				
Other income (expense)	(245)	5,398	5,643	104.5
Interest income	150	427	(277)	(64.9)
Net loss	$ (1,327,250)	$ (1,822,518)	$ (495,268)	(27.2)

Research and Development Expenses

Research and development ("R&D") expenses for the quarter ended March 31, 2019 decreased by approximately $0.2 million, or 34.3% to $0.5 million from $0.7 million in the comparable quarter in 2018. The table below sets forth the R&D costs incurred by the Company by category of expense for the quarters ended March 31, 2019 and 2018:

	Quarter ended,	
Category of Expense	March 31, 2019	March 31, 2018
Outside services and contract research organizations	$ 354,345	$ 510,378
Salaries and wages	79,285	66,937
Share-based expense	11,418	60,345
Other	18,734	68,611
Total research and development expense	$ 463,782	$ 706,271

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 three months ended March 31, 2019 as compared to same period in the prior year. Site and patient costs related to the trial were generally lower as we closed patient enrollment during the first quarter of 2019. Salaries and wages increased during the three months ended March 31, 2019 due to slightly higher employee benefit costs. Share-based expense decreased during the three months ended March 31, 2019 as compared to the same period in the prior year primarily due to income related to the revaluation of warrants issued to Serum Institute in 2016. Other expense decreased during the three months ended March 31, 2019 primarily due to lower rent costs as we relocated our corporate headquarters in January 2019.

General and Administrative Expenses

General and administrative expenses decreased by approximately $0.3 million or 23.1% for the quarter ended March 31, 2019, to $0.9 million from $1.1 million in the comparable quarter in 2018. Payroll and share-based expense decreased due to lower headcount during the three months ended March 31, 2019 compared to the same period in the prior year and facility costs decreased due to the relocation of our corporate headquarters in January 2019. These decreases were offset by slightly higher consulting costs in first three months of 2019 compared to the first quarter of 2018.

Other Income (Expense)

Other expense was $245 for the three months ended March 31, 2019 compared to $5,398 of other income for the same period in 2018. This increase in expense was primarily related to a reduction in foreign currency transactions and related changes in foreign currency exchange rates during the first quarter of 2019 as compared to the same period in 2018.

Interest Income (Expense)

Interest income was $150 for the three months ended March 31, 2019 and slightly decreased from interest income of $427 in the same period in the prior year.

Comparison of Year ended December 31, 2018 to Year ended December 31, 2017

The table below sets forth the comparison of our historical results of operations for the year ended December 31, 2018 to the year ended December 31, 2017.

Description	2018	2017	Increase (Decrease)	Percentage Change
Revenues:				
Licenses and collaboration services	$ –	$ 7,585,000	$ (7,585,000)	(100.0)%
Operating costs and expenses:				
Cost of research and development revenue	–	(156,119)	(156,119)	(100.0)%
Research and development	(2,883,952)	(4,060,000)	(1,176,048)	(29.0)%
General and administrative	(4,392,375)	(6,937,643)	(2,545,268)	(36.7)%
Loss from operations	$ (7,276,327)	$ (3,568,762)	$ 3,707,565	103.9%
Other income (expense):				
Other expense	(24,640)	(24,552)	88	0.4%
Interest income (expense)	509	(1,818)	(2,327)	(128.0)%
Net loss	$ (7,300,458)	$ (3,595,132)	$ 3,705,326	103.1%

Revenue

For the year ended December 31, 2017, revenue represented license and collaboration services. We did not receive any license or collaboration service revenue for the year ended December 31, 2018.

In October 2017, we entered into a Right to Sublicense Agreement (the “Sublicense Agreement”) with Baxalta Incorporated, Baxalta US Inc., and Baxalta GmbH (collectively, with their affiliates “Baxalta”) wholly-owned subsidiaries of Takeda Pharmaceuticals Co., Ltd. (“Takeda”), formerly Shire plc . Pursuant to the Sublicense Agreement, Baxalta paid us a one-time payment of seven million five hundred thousand dollars ($7,500,000) in November 2017 and agreed to pay us single digit royalty payments based upon net sales of the licensed patents in connection with products related to the treatment of blood and bleeding disorders (“Covered Products”) throughout the term, each of which is conditioned upon the performance of the sublicense contemplated by the Sublicense Agreement. We recognized revenue of $7.5 million in 2017 related to this payment.

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

Cost of Revenue

There was no cost of revenue for the year ended December 31, 2018. Cost of research and development revenue represents collaboration services related to research and development programs conducted on behalf of third-parties in 2017.

Research and Development Expense

R&D expenses decreased $1.2 million, or 29.0% to $2.9 million from $4.1 million in the comparable period in 2017. The table below sets forth the research and development expenses incurred by category of expense for the years ended December 31, 2018 and 2017.

	Year ended December 31,	
Category of Expense	2018	2017
Outside services and Contract Research Organizations	$ 2,242,658	$ 3,094,583
Share-based expense	203,031	101,400
Personnel costs	280,118	568,376
Other	158,145	295,641
Total research and development expense	$ 2,883,952	$ 4,060,000

The decrease in outside services and contract research organizations expense was primarily due to our internal development efforts being solely focused on our oncology product, XBIO-101, during the year ended December 31, 2018 due to capital constraints. For the year ended December 31, 2017 outside services and contract research organizations included costs associated with other programs and development efforts but such costs were not continued in 2018. Share-based expense increased during the year ended December 31, 2018 as compared to the same period in the prior year primarily due to expense related to warrants issued to Serum Institute in 2016. Salaries and wages decreased during the year ended December 31, 2018 as we reduced our R&D headcount in the second half of fiscal year 2017 due to our limited internal development efforts. Other expense decreased during the year ended December 31, 2018 primarily due to lower laboratory costs in 2018 as we discontinued our internal development efforts in the second half of 2017.

General and Administrative Expense

General and administrative expenses decreased by approximately $2.5 million or 36.7% for the year ended December 31, 2018 to $4.4 million from $6.9 million in the comparable period in 2017. Employee-related costs, including shared-based costs and travel, legal, accounting, investor and public relations costs all decreased during the year ended December 31, 2018 compared to the year ended December 31, 2017 as we significantly reduced our discretionary spending due to our capital constraints. In addition, expense for the year ended December 31, 2017 included approximately $0.6 million in accrued severance related to a settlement agreement with our former Chief Executive Officer who separated from the Company in November 2017.

Other Expense

Other expense was approximately $25,000 for the year ended December 31, 2018 and was relatively unchanged from the prior year.

Interest Income (Expense)

We earned $500 of net interest income for the year ended December 31, 2018 compared to net interest expense of $2,000 in the year ended December 31, 2017 due to lower interest expense on our operating lease.

Liquidity and Capital Resources

We incurred a net loss of approximately $1.3 million for the three months ended March 31, 2019 and had an accumulated deficit of $154.6 million at March 31, 2019 as compared to an accumulated deficit of approximately $153.2 million at December 31, 2018. Working capital (deficit) was approximately $1.2 million and $(0.4) million at March 31, 2019 and December 31, 2018, respectively. During the quarter ended March 31, 2019, our working capital increased by $1.6 million due to the issuance of common stock and warrants in our March 2019 offering resulting in $2.7 million of net proceeds to us. This increase in working capital was partially offset by our net loss for the quarter and an increase in deferred costs associated with our acquisition of the XCART platform technology. We expect to continue incurring losses for the foreseeable future and will need to raise additional capital or pursue other strategic alternatives in the very near term in order to continue the pursuit of our business plan and continue as a going concern.

Our principal source of liquidity consists of cash. At March 31, 2019, we had approximately $2.0 million in cash and $2.0 million in current liabilities. At December 31, 2018, we had approximately $0.6 million in cash and $1.6 million in current liabilities. At December 31, 2017, we had approximately $5.5 million in cash and $1.9 million in accounts payable and accrued expenses.

We have historically relied upon sales of our equity securities to fund our operations. Since 2005, we have raised approximately $63.0 million in proceeds from offerings of our common and preferred stock. We have also received approximately $20.0 million from revenue producing activities from 2005 through March 31, 2019. 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.

We estimate that our existing resources will only be able to fund our planned operations, existing obligations and contractual commitments through the first half of 2019. This estimate is based on our current expectations regarding projected staffing expenses, working capital requirements, costs to close the XCART transaction, capital expenditure plans and anticipated revenues. Given our current working capital constraints, we have attempted to minimize cash commitments and expenditures for external research and development and general and administrative services to the greatest extent practicable. We will need to raise additional working capital in the very near term in order to fund our future operations, including our development efforts associated with the XCART platform technology.

We have no committed sources of additional capital. Our management believes that we have access to capital resources through possible public or private equity offerings, debt financings, corporate collaborations, related party funding or other means. In March 2019, we raised $3.1 million in a registered direct common stock offering resulting in $2.7 million of net proceeds to us. However, we have not secured any commitment for additional financing at this time. The terms, timing and extent of any future financing will depend upon several factors including the achievement of progress in our clinical development programs, our ability to identify and enter into licensing or other strategic arrangements and factors related to financial, economic and market conditions, many of which are beyond our control.

Management evaluates whether there are conditions or events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern within one year after the date that the financial statements are issued. We have incurred substantial losses since our inception, and we expect to continue to incur operating losses in the near-term. These factors raise substantial doubt about our ability to continue as a going concern. As a result, our independent registered public accounting firm included an explanatory paragraph in its report on our audited financial statements for the year ended December 31, 2018 expressing doubt as to our ability to continue as a going concern. We will need to raise additional capital in order to sustain our operations. If we are unable to secure additional funds on a timely basis or on acceptable terms, we may be required to defer, reduce or eliminate significant planned expenditures, restructure, curtail or eliminate some or all of our development programs or other operations, reduce general and administrative expenses, and delay or cease the purchase of clinical research services, dispose of technology or assets, pursue an acquisition of our company by another party at a price that may result in a loss on investment for our stockholders, enter into arrangements that may require us to relinquish rights to certain of our drug candidates, technologies or potential markets, file for bankruptcy or cease operations altogether. The accompanying consolidated financial statements do not include any adjustments related to the recoverability or classification of asset carrying amounts or the amounts and classification of liabilities that may result should we be unable to continue as a going concern.

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

Summary of Cash Flows

Comparison of Three Months ended March 31, 2019 to Three Months ended March 31, 2018

Cash Flows from Operating Activities

Cash flows used in operating activities for the three months ended March 31, 2019 totaled approximately $1.3 million, which was primarily due to our net loss for the period and deferred costs related to the XCART acquisition.

Cash flows used in operating activities for the quarter ended March 31, 2018 totaled approximately $1.7 million, which was primarily due to our net loss of approximately $1.8 million, offset by non-cash charges of $0.4 million, and a decrease in accrued expenses.

Cash Flows from Investing Activities

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

For the three months ended March 31, 2018 there were no cash sources or uses from investing activities.

Cash Flow from Financing Activities

Cash flows from financing activities for the three months ended March 31, 2019 totaled approximately $2.7 million representing net proceeds from the issuance of common stock and warrants.

For the three months ended March 31, 2018 there were no cash sources or uses from financing activities.

Comparison of Year ended December 31, 2018 to Year ended December 31, 2017

Cash Flows from Operating Activities

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

Cash Flows from Investing Activities

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.

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

As of December 31, 2018, there were no material commitments for capital expenditures.

Cash Flow from Financing Activities

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

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

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 March 31, 2019 and December 31, 2018, aggregated by type:

	Payments Due by Period As of March 31, 2019				
	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Operating lease obligations	$ 54,575	$ 40,533	$ 14,042	$ –	$ –
Total	$ 54,575	$ 40,533	$ 14,042	$ –	$ –

	Payments Due by Period As of December 31, 2018				
	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Operating lease obligations	$ 24,583	$ 24,583	$ –	$ –	$ –
Total	$ 24,583	$ 24,583	$ –	$ –	$ –

On January 7, 2019, we entered into a new office lease in Framingham, MA. The sublease is for 21 months through September 30, 2020 with a total contractual obligation of approximately $50,000.

Recent Accounting Standards

Refer to Note 2, *Summary of Significant Accounting Policies*, of the financial statements for the three months ended March 31, 2019 and the years ended December 31, 2018 and 2017 included in this prospectus.

Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

Not applicable.

MANAGEMENT

Directors and Executive Officers

Set forth below is the name, age, position and brief biographies of each of our executive officers and directors as of April 26, 2019.

Name	Age	Position
Jeffrey Eisenberg	53	Chief Executive Officer and Director
Dr. Curtis Lockshin	58	Chief Scientific Officer
James Parslow	54	Chief Financial Officer and Corporate Secretary
Dr. James E. Callaway	62	Director (1), (2), (3)
Firdaus Jal Dastoor, FCS	66	Director (1), (2)
Dr. Dmitry Genkin	50	Director
Roman Knyazev	38	Director
Dr. Roger Kornberg	72	Director (3)
Adam Logal	41	Director (1), (2), (3)

(1) Member of the Audit Committee
(2) Member of the Compensation Committee
(3) Member of the Nominating and Corporate Governance Committee

Jeffrey F. Eisenberg was appointed our Chief Executive Officer on October 26, 2017, after serving as Chief Operating Officer since December 2, 2016, and has served as a member of our Board of Directors ("Board") since July 2016. Mr. Eisenberg previously worked at Noven Pharmaceuticals, Inc. ("Noven"), a subsidiary of Hisamitsu Pharmaceutical, Inc., where he held various positions of increasing responsibility, most recently serving from 2009-2016 as Noven's president, chief executive officer and as a member of its board of directors. Mr. Eisenberg obtained his J.D. at Columbia University Law School and a B.S. in Economics from the Wharton School, University of Pennsylvania. We believe Mr. Eisenberg's significant life science executive experience and leadership experience in the areas of R&D, operations, manufacturing/quality, business development, strategic partnering, product development, commercialization, and human resources provides him with the appropriate set of skills to serve as a member of our Board.

Dr. Curtis A. Lockshin initially joined us on a part-time basis in March 2014 as our Vice President of Research & Operations and was appointed our Chief Scientific Officer effective January 1, 2017. Dr. Lockshin has held several management positions at development and commercial stage biotechnology companies, with experience including discovery, preclinical and clinical development, as well as commercial manufacturing. Since May 2013, he has held the position of president and chief executive officer of Guardum Pharmaceuticals LLC ("Guardum"), a wholly owned subsidiary of PJSC Pharmsynthez, our controlling stockholder, a position which he continues to hold in addition to his position with us. Dr. Lockshin does not receive a salary for these services but did receive medical benefits and was covered under Guardum's health plan through July 31, 2018. In addition, Dr. Lockshin has served as an officer or consultant of several biotechnology companies on a part-time basis, including as an officer of a series of related companies following multiple mergers beginning as chief executive officer and director of SciVac Therapeutics, Inc. and its subsidiary SciVac, Ltd., from September 2014 until July 2016. After SciVac Therapeutics, Inc.'s merger with VBI Vaccines, Inc. in July 2016, Dr. Lockshin served as chief technical officer of the merged company until December 2016. Dr. Lockshin is currently serving as a member of the board of directors of Phio Pharmaceuticals Corporation, a publicly traded clinical-stage RNAi company, a position he has held since April 2013. Dr. Lockshin has an S.B. in Life Sciences and a Ph.D. in Biological Chemistry from the Massachusetts Institute of Technology. Since April 2004, Dr. Lockshin has also served as a member of the board of directors of the Ruth K. Broad Biomedical Research Foundation, a Duke University Support Corporation that supports basic research related to Alzheimer's disease and neurodegeneration via intramural, extramural and international grants.

James Parslow was appointed our Chief Financial Officer on April 3, 2017. Mr. Parslow most recently served as Chief Financial Officer, Treasurer and Secretary of World Energy Solutions, Inc., a publicly-traded business-to-business e-commerce company brokering energy and environmental commodities, from 2006 until its acquisition by EnerNOC, Inc. in 2015. Since 2015, he has served as an independent consultant providing interim chief financial officer services to multiple emerging technology companies. Mr. Parslow is a Certified Public Accountant with 30 years of experience serving private and public companies in the biotech, alternative energy, online auction, and high-tech manufacturing industries. He holds an A.B. in Economics and Accounting from the College of the Holy Cross and an M.B.A. with a concentration in Finance from Bentley University.

James E. Callaway was appointed to the Board on August 14, 2017. Dr. Callaway has over 30 years of experience in the execution of product development operations for biotherapeutics and currently serves as CEO of KalGene, a privately-held preclinical company focused on delivery of a proprietary development candidate to alter the course of Alzheimer's Disease. Dr. Callaway is a seasoned CEO within the venture-backed biotech community and over the course of his career he has built and operated several companies, transforming each from research companies to clinical stage operating entities. Since 2016, he has also served as a Corporate Strategy Consultant at Callaway Innovations. From 2012 until 2016, Dr. Callaway was President and Chief Executive Officer of ArmaGen, Inc. and from 2008 until 2012, served as President and CEO of CEBIX, Inc. Prior to these efforts, Dr. Callaway held multiple senior leadership positions at Elan Pharmaceuticals, including simultaneously acting as Head of Development and overseeing the complex partnership with Wyeth Pharmaceuticals in the Alzheimer's disease immunotherapy program. He has developed antibodies for a wide-range of therapeutic applications over the past two decades, including treatments of multiple sclerosis (Tysabri®: pharmaceutical development), Alzheimer's disease (bapineuzumab: Program Executive), and blood-brain barrier transport, and has worked with the United States Food and Drug Administration on multiple orphan drug development programs. We believe Dr. Callaway's significant life sciences executive, leadership and strategic experience in the area of biotherapeutics provides him with the appropriate set of skills to serve as a member of our Board.

Firdaus Jal Dastoor, FCS**,** was initially appointed as a member of our Board in January 2014 pursuant to terms of the agreement of our acquisition of Xenetic U.K. He has been employed by the Cyrus Poonawalla Group, a conglomerate in India with interests in horse racing and breeding, biotech, engineering and hotels, in business development strategies and operational roles since October 1981. Mr. Dastoor is currently a Group Director in charge of Finance and Corporate Affairs and Company Secretary of the Serum Institute of India Private Limited at the Cyrus Poonawalla Group, one of our significant stockholders. He is a Fellow Member of The Institute of Company Secretaries of India since 1990. Mr. Dastoor is on the board of several private companies operating in the fields of engineering products, life sciences and biotech, international trade, financial services and quality standards certifications. Mr. Dastoor received a B.A. in Commerce from the University of Poona. We believe Mr. Dastoor's knowledge of investments in the life sciences and biotechnology industries, and his finance and business development background provide him with the appropriate set of skills to serve as a member of our Board.

Dmitry Genkin was appointed to the Board on August 14, 2017. Dr. Genkin currently serves on the Company's Scientific Advisory Board and previously served on the Company's Board of Directors from 2004-2016. He has the Russian equivalent of an MD in Internal Therapy and studied drug delivery under Professor Gregory Gregoriadis at The School of Pharmacy, University of London in 1992, as well as the Department of Clinical Pharmacology at Karolinska Hospital, Stockholm from 1992 until 1993. Since 2005, Dr. Genkin has served as Executive Chairman of PJSC Pharmsynthez, a public company and Xenetic's majority stockholder. Prior to that time, Dr. Genkin headed a number of Russia's largest pharmaceutical companies including Pharmavit, which had 27% of the Russian pharmaceutical market. In 1998, he was awarded the silver medal by the Russian Natural Science Academy. We believe Dr. Genkin's significant life sciences, biotechnology and international background provide him with the appropriate set of skills to serve as a member of our Board.

Roman Knyazev has served as a member of our Board since April 2014. Mr. Knyazev has served in various positions at Rusnano Moscow since 2009, most recently as its Investment Director. He also serves on the boards of directors of Nanolek, PETAR, PJSC Pharmsynthez, and SynBio LLC. Mr. Knyazev is a Fellow of the Kauffman Fellows Program. We believe Mr. Knyazev's experience investing in clinical stage biotechnology companies provides him with the appropriate set of skills to serve as a member of our Board.

Dr. Roger Kornberg has served as a member of our Board since February 2016. Dr. Kornberg is a member of the U.S. National Academy of Sciences and the Winzer Professor of Medicine in the Department of Structural Biology at Stanford University. He earned his B.S. in chemistry from Harvard University in 1967 and his Ph.D. in chemical physics from Stanford in 1972. He became a postdoctoral fellow at the Laboratory of Molecular Biology in Cambridge, England and then an assistant professor of biological chemistry at Harvard Medical School in 1976, before moving to his present position as professor of structural biology at Stanford Medical School in 1978. In 2006, Dr. Kornberg was awarded the Nobel Prize in Chemistry in recognition for his studies of the molecular basis of Eukaryotic Transcription, the process by which DNA is copied to RNA. Dr. Kornberg is also the recipient of several awards, including the 2001 Welch Prize, the highest award granted in the field of chemistry in the United States, and the 2002 Leopald Mayer Prize, the highest award granted in the field of biomedical sciences from the French Academy of Sciences. We believe Dr. Kornberg's prior experience serving on the boards of directors of large organizations as well as his scientific background provides him with the appropriate set of skills to serve as a member of our Board.

Adam Logal was appointed to the Board in August 2017. Mr. Logal has over 16 years of experience in the biopharmaceuticals industry. Since April 2014, Mr. Logal has served as Senior Vice President, Chief Financial Officer, Chief Accounting Officer and Treasurer of OPKO Health, Inc. and from March 2007 until April 2014 served as OPKO's Vice President of Finance, Chief Accounting Officer and Treasurer. Mr. Logal served as a director of VBI Vaccines, Inc., a publicly-traded company, from May 2015 through October 2018 and served as its Audit Committee Chairman. Prior to joining OPKO, Mr. Logal served in various financial management roles at Nabi Biopharmaceuticals, a commercial stage biopharmaceutical company. Mr. Logal is a strategic finance executive with extensive experience in SEC compliance and reporting, domestic and international finance, strategic planning, cash flow management, budgeting, taxation, treasury and business development. We believe Mr. Logal's extensive financial experience with public companies in the life sciences industry provides him with appropriate set of skills to serve as a member of our Board.

There are no family relationships among any of our directors and executive officers and, to the best of our knowledge, none of our directors or executive officers has, during the past ten years, been involved in any legal proceedings which are required to be disclosed pursuant to the rules and regulations of the SEC.

Our Board of Directors

Currently, the Board consists of seven (7) members: Jeffrey F. Eisenberg, Dr. James E. Callaway, Firdaus Jal Dastoor, Dr. Dmitry Genkin, Roman Knyazev, Dr. Roger Kornberg, and Adam Logal. Prior to August 2017, we combined the positions of Chief Executive Officer and Board Chair. As of August 2017, we separated the roles of Chief Executive Officer and Board Chair in recognition of the differences between the two roles. The Board of Directors is currently chaired by independent director, Adam Logal, and our Chief Executive Officer, Jeffrey Eisenberg, is our only employee-director. The Chief Executive Officer is responsible for setting the strategic direction for the Company and the day to day leadership and performance of the Company, while the Board Chair is responsible for leading the Board in the execution of its fiduciary duties. The Board Chair presides over meetings of the full Board. While we recognize that different board leadership structures may be appropriate for companies in different situations, we believe our current leadership structure is the optimal structure for the Company at this time. Directors shall hold office for a one-year term or until their successors have been duly elected and qualified. Vacancies on the Board resulting from death, resignation, disqualification, removal, or other causes can be filled by the affirmative vote of a majority of the directors then in office. Any director so elected, shall hold office for the remainder of the full term of the director for which the vacancy was created or occurred and until such director's successor shall have been duly elected and qualified.

Committees of the Board

The Board has three standing committees: an Audit Committee, a Compensation Committee, and a Nominating and Corporate Governance Committee. The Board also has two special committees: an Expense Management and Financing Oversight Committee and a Strategic Alternatives Committee. The Expense Management and Financing Oversight Committee was formed in October 2017. The Strategic Alternatives Committee was formed in March 2018. The Company has adopted charters to govern the conduct, authority and responsibilities of each of the Audit Committee, Compensation Committee and Nominating and Corporate Governance Committee.

Audit Committee

The Audit Committee of the Board of Directors was established by the Board in accordance with Section 3(a)(58)(A) of the Exchange Act, to oversee the Company's corporate accounting and financial reporting processes and audits of its financial statements. For this purpose, the Audit Committee performs several functions. The Audit Committee evaluates the performance of and assesses the qualifications of the independent auditors; determines and approves the engagement of the independent auditors; determines whether to retain or terminate the existing independent auditors or to appoint and engage new independent auditors; reviews and approves the retention of the independent auditors to perform any proposed permissible non-audit services; monitors the rotation of partners of the independent auditors on the Company's audit engagement team as required by law; reviews and approves or rejects transactions between the Company and any related persons; confers with management and the independent auditors regarding the effectiveness of internal control over financial reporting; establishes procedures, as required under applicable law, for the receipt, retention and treatment of complaints received by the Company regarding accounting, internal accounting controls or auditing matters and the confidential and anonymous submission by employees of concerns regarding questionable accounting or auditing matters; and meets to review the Company's annual audited financial statements and quarterly financial statements with management and the independent auditor, including a review of the Company's disclosures under the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section of the Company's Annual Report to Stockholders on Form 10-K.

For the year ended December 31, 2018, the Audit Committee was composed of three directors: Mr. Dastoor, Dr. Callaway, and Mr. Logal (chair). The Audit Committee met five times during the year ended December 31, 2018. The Board has adopted a written Audit Committee charter that is available to stockholders on the Company's website at http://ir.xeneticbio.com/.

The Board of Directors reviews the NASDAQ listing standards definition of independence for Audit Committee members on an annual basis and has determined that all current members of our Audit Committee are independent (as independence is currently defined in Rule 5605(c)(2)(A)(i) and (ii) of the NASDAQ listing standards).

The Board of Directors has also determined that Mr. Logal qualifies as an "audit committee financial expert," as defined in applicable SEC rules. The Board made a qualitative assessment of Mr. Logal's level of knowledge and experience based on a number of factors, including his formal education and experience as a chief financial officer.

Compensation Committee

For the year ended December 31, 2018, the Compensation Committee was composed of three directors: Mr. Dastoor, Dr. Callaway (chair), and Mr. Logal. All current members of our Compensation Committee are independent (as independence is currently defined in Rule 5605(d)(2) of the NASDAQ listing standards). The Board has adopted a written Compensation Committee charter that is available to stockholders on the Company's website at http://ir.xeneticbio.com/. The Compensation Committee of the Board acts on behalf of the Board to review, recommend for adoption and oversee our compensation strategy, policies, plans and programs, including:

- establishment of corporate and individual performance objectives relevant to the compensation of our executive officers and directors and evaluation of performance in light of these stated objectives;
- review and approval of the compensation and other terms of employment or service of our Chief Executive Officer; and
- administration of our equity compensation plans, pension and profit-sharing plans, deferred compensation plans and other similar plan and programs.

The Compensation Committee determines salaries, incentives and other forms of compensation for the Chief Executive Officer and our executive officers and reviews and makes recommendations to the Board with respect to director compensation. The Compensation Committee meets without the presence of executive officers when approving or deliberating on executive officer compensation, but may invite the Chief Executive Officer to be present during the approval of, or deliberations with respect to, other executive officer compensation. The Compensation Committee reviews and approves the terms of offer letters, employment agreements, severance agreements, change-in-control agreements, indemnification agreements and other material agreements between us and our executive officers. In addition, the Compensation Committee administers our stock incentive compensation and equity-based plans.

Nominating and Corporate Governance Committee

The Nominating and Corporate Governance Committee of the Board is responsible for identifying, reviewing and evaluating candidates to serve as directors of the Company (consistent with criteria approved by the Board), reviewing and evaluating incumbent directors, recommending to the Board for selection candidates for election to the Board of Directors, making recommendations to the Board regarding the membership of the committees of the Board, and developing a set of corporate governance principles for the Company. For the year ended December 31, 2018, the Nominating and Corporate Governance Committee was composed of three directors: Dr. Kornberg, Dr. Callaway (chair), and Mr. Logal. All current members of the Nominating and Corporate Governance Committee are independent (as independence is currently defined in Rule 5605(a)(2) of the NASDAQ listing standards). The Nominating and Corporate Governance Committee met once during 2018. The Board has adopted a written Nominating and Corporate Governance Committee charter that is available to stockholders on the Company's website at http://ir.xeneticbio.com/.

The Nominating and Corporate Governance Committee believes that candidates for director should have certain minimum qualifications, including the ability to read and understand basic financial statements, being over 21 years of age and having the highest personal integrity and ethics. The Nominating and Corporate Governance Committee also intends to consider such factors as possessing relevant expertise upon which to be able to offer advice and guidance to management, having sufficient time to devote to the affairs of the Company, demonstrated excellence in his or her field, having the ability to exercise sound business judgment and having the commitment to rigorously represent the long-term interests of the Company's stockholders. However, the Nominating and Corporate Governance Committee retains the right to modify these qualifications from time to time. Candidates for director nominees are reviewed in the context of the current composition of the Board, the operating requirements of the Company and the long-term interests of stockholders. In conducting this assessment, the Nominating and Corporate Governance Committee typically considers diversity, age, skills and such other factors as it deems appropriate, given the current needs of the Board and the Company, to maintain a balance of knowledge, experience and capability.

While we do not have a formal diversity policy with respect to Board composition, the Board believes it is important for the Board to have diversity of knowledge base, professional experience and skills, and the Nominating and Corporate Governance Committee takes these qualities into account when considering director nominees for recommendation to the Board.

The Nominating and Corporate Governance Committee will consider director candidates recommended by stockholders. A stockholder who wishes to suggest a prospective nominee for the Board of Directors should notify the Company's Secretary or any member of the Nominating and Corporate Governance Committee in writing and include any supporting material the stockholder considers appropriate. In addition, the Company's Amended and Restated Bylaws contain provisions addressing the process by which a stockholder may nominate an individual to stand for election to the Board of Directors at its Annual Meeting of Stockholders. In order to nominate a candidate for director, a stockholder must give timely notice in writing to the Company's Secretary and otherwise comply with the provisions of our Amended and Restated Bylaws. To be timely, our Amended and Restated Bylaws provide that we must have received the notice not less than 90 days or more than 120 days prior to the one-year anniversary of the date of the previous year's Annual Meeting of Stockholders (the "Anniversary"); provided, however, that in the event that the date of next year's Annual Meeting is more than 30 days before or more than 30 days after the Anniversary, notice must be delivered not earlier than the close of business on the 120th day prior to next year's Annual Meeting and not later than the close of business on the later of (i) the 90th day prior next year's Annual Meeting or (ii) the close of business on the 10th day following the day on which public announcement of the date of next year's Annual Meeting is first made by us. Information required by our Amended and Restated Bylaws to be in the notice includes: (A) all information relating to such person that is required to be disclosed in solicitations of proxies for election of directors, or is otherwise required, in each case, pursuant to Regulation 14A under the Securities Exchange Act of 1934, as amended (including such person's written consent to being named in the proxy statement as a nominee and to serving as a director, if elected); (B) a description of all direct and indirect compensation and other material monetary agreements, arrangements and understandings during the past three (3) years, and any other material relationships, between or among such stockholder, the beneficial owner, if any, on whose behalf any such proposal or nomination is being made, and their respective affiliates and associates, on the one hand, and each proposed nominee, and his or her respective affiliates and associates, on the other hand, including, without limitation, all information that would be required to be disclosed pursuant to Item 404 of Regulation S-K promulgated under the Securities Act of 1933, as amended, if such stockholder, such beneficial owner, or any affiliate or associate thereof, were the "registrant" for purposes of such rule and the nominee were a director or executive officer of such registrant; (C) to the extent known by the stockholder, the name and address of any other security holder of the Company who owns, beneficially or of record, any securities of the Company and who supports any nominee proposed by such stockholder; and (D) a questionnaire and a representation and agreement, completed and signed by such person, as required by our Amended and Restated Bylaws.

Stockholder nominations must be made in accordance with the procedures outlined in, and include the information required by, our Amended and Restated Bylaws and must be addressed to our Corporate Secretary, c/o Xenetic Biosciences, Inc., 40 Speen Street, Suite 102, Framingham, Massachusetts 01701. You can obtain a copy of our Amended and Restated Bylaws by writing to the Corporate Secretary at this address.

Independence of the Board of Directors

As required under the NASDAQ listing standards, a majority of the members of a listed company's board of directors must qualify as "independent," as affirmatively determined by the Board of Directors. The Board consults with advisors to ensure that the Board's determinations are consistent with relevant securities and other laws and regulations regarding the definition of "independent," including those set forth in pertinent listing standards of NASDAQ, as in effect from time to time.

Consistent with these considerations, after review of all relevant identified transactions or relationships between each director, or any of his or her family members, and the Company, its senior management and its independent auditors, the Board affirmatively determined that the following directors were independent directors within the meaning of the applicable NASDAQ listing standards for the period during which they served as a member of the Board during the year ended December 31, 2018: Dr. Callaway, Mr. Dastoor, Dr. Kornberg, and Mr. Logal. In addition, the Board has determined that Mr. Vinogradov will be an independent director within the meaning of the applicable NASDAQ listing standards.

During the year ended December 31, 2018, all members of our Audit Committee, Nominating and Corporate Governance Committee, and Compensation Committee were independent (as independence is currently defined in Rule 5605 of the NASDAQ listing standards).

Board Leadership Structure

Prior to August 2017, we combined the positions of Chief Executive Officer and Board Chair. As of August 2017, we separated the roles of Chief Executive Officer and Board Chair in recognition of the differences between the two roles. The Board of Directors is currently chaired by independent director, Adam Logal, and our current Chief Executive Officer, Jeffrey Eisenberg, is our only employee-director. The Chief Executive Officer is responsible for setting the strategic direction for the Company and the day to day leadership and performance of the Company, while the Board Chair is responsible for leading the Board in the execution of its fiduciary duties. The Board Chair presides over meetings of the full Board. While we recognize that different board leadership structures may be appropriate for companies in different situations, we believe our current leadership structure is the optimal structure for the Company at this time.

Role of the Board in Risk Oversight

Our management is principally responsible for defining the various risks facing the Company, formulating risk management policies and procedures, and managing our risk exposures on a day-to-day basis. The Board's principal responsibility in this area is to ensure that sufficient resources, with appropriate technical and managerial skills, are provided throughout the Company to identify, assess and facilitate processes and practices to address material risk and to monitor our risk management processes by informing itself concerning our material risks and evaluating whether management has reasonable controls in place to address the material risks. The involvement of the Board in reviewing our business strategy is an integral aspect of the Board's assessment of management's tolerance for risk and its determination of what constitutes an appropriate level of risk for the Company.

Stockholder Communications with the Board Of Directors

Historically, we have not provided a formal process related to stockholder communications with the Board. All communications to our Board, our Board committees or any individual director, must be in writing and addressed to our Corporate Secretary, c/o Xenetic Biosciences, Inc., 40 Speen Street, Suite 102, Framingham, Massachusetts 01701. All communications will be reviewed by the Secretary and, unless otherwise indicated in such communication, submitted to the Board or an individual director, as appropriate.

Code of Business Conduct and Ethics

We have adopted the Xenetic Biosciences, Inc. Code of Business Conduct and Ethics that applies to all of our employees, officers and directors, including our principal executive officer, principal financial officer and principal accounting officer. The Code of Business Conduct and Ethics is available on our website, www.xeneticbio.com, under "Investors" at "Corporate Governance." If we make any substantive amendments to the Code of Business Conduct and Ethics or grant any waiver from a provision of the Code of Business Conduct and Ethics to any executive officer or director, we intend to promptly disclose the nature of the amendment or waiver on our website, to the extent required by the applicable rules and exchange requirements.

Meetings of the Board of Directors

The Board of Directors met five times during the last fiscal year. Each Board member attended 75% or more of the aggregate number of meetings of the Board and of the committees on which she or he served that were held during the portion of the last fiscal year for which she or he was a director or committee member, except as follows: Dr. Kornberg attended 40% of the Board meetings during 2018. At the Company's last annual meeting of stockholders, which was held in November of 2018, six of our Board members attended the meeting and were available to be heard by those present at the meeting.

DIRECTOR AND EXECUTIVE COMPENSATION

Summary Compensation Table

The following table sets forth, for the years ended December 31, 2018 and 2017, the compensation information for Jeffrey Eisenberg, our Chief Executive Officer, Dr. Curtis Lockshin, our Chief Scientific Officer, and James Parslow, our Chief Financial Officer. We refer to Messrs. Eisenberg, Lockshin, and Parslow herein, collectively, as our "named executive officers."

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)	Option Awards[1] ($)	Non-Equity Incentive Plan Compensation ($)	All Other Compensation ($)	Total ($)
Jeffrey F. Eisenberg,	2018	$ 300,000	$ –	$ –	$ –	$ –	$ 18,333 [2]	$ 318,333
Chief Executive Officer	2017	$ 300,000 [3]	$ –	$ 105,720	$ 375,389	$ –	$ 34,381	$ 815,490
James Parslow,	2018	$ 265,000	$ –	$ –	$ –	$ –	$ 22,595 [4]	$ 287,595
Chief Financial Officer	2017	$ 198,750 [5]	$ –	$ –	$ 667,216	$ –	$ 24,830	$ 890,796
Dr. Curtis Lockshin,	2018	$ 250,000	$ –	$ –	$ –	$ –	$ 9,584 [6]	$ 259,584
Chief Scientific Officer	2017	$ 250,000 [7]	$ –	$ –	$ 625,316	$ –	$ 2,523	$ 877,839

(1) The amounts represent the aggregate grant date fair value of stock options granted in the applicable fiscal year, computed in accordance with FASB ASC Topic 718, excluding the effect of estimated forfeitures. Assumptions used in the calculation of this amount are set forth in Note 10 to our audited consolidated financial statements included in Item 8 of the Original Filing. Mr. Eisenberg, Mr. Parslow, and Dr. Lockshin were granted options to purchase 250,000 shares, 175,000 shares and 175,000 shares of common stock, respectively, during 2017. In addition, Mr. Eisenberg was granted 50,000 restricted stock units in 2017.

(2) Includes $18,333 for health and welfare plans.

(3) Mr. Eisenberg was appointed our Chief Operating Officer in December 2016 and Chief Executive Officer in October 2017. Mr. Eisenberg served as a director of the Company from July 2016 through November 2016. As an employee, Mr. Eisenberg no longer receives compensation for serving as a member of our Board.

(4) Includes $22,595 for health and welfare plans.

(5) Mr. Parslow was appointed our Chief Financial Officer in April 2017.

(6) Includes $9,584 for health and welfare plans.

(7) Dr. Lockshin was appointed our Chief Scientific Officer in January 2017.

Outstanding Equity Awards at Fiscal Year-End

The following table sets forth certain information with respect to outstanding equity awards held by our named executive officers at December 31, 2018.

	Option Awards				Stock Awards	
Name	Number of Securities Underlying Unexercised Options, Exercisable	Number of Securities Underlying Unexercised Options, Unexercisable	Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested	Market Value of Shares or Units of Stock That Have Not Vested ($)
Jeffrey F. Eisenberg	154,900[1]	75,100[1]	3.40	12/2/2026	–	–
	41,667[2]	208,333[2]	2.11	10/26/2027	–	–
	–	–	–	–	33,333[3]	$ 70,480
James Parslow	58,333[4]	116,667[4]	4.57	4/3/2027	–	–
Curtis Lockshin	14,546[5]	–	4.59	12/31/2024	–	–
	15,152[6]	–	4.59	9/6/2025	–	–
	58,333[7]	116,667[7]	4.30	1/1/2027	–	–

(1) 4,700 shares vested 100% on the date of grant. Remainder vests one-third upon the first anniversary of the grant date, one-third of the remaining amount upon the second anniversary of the grant date and one-third of the remaining amount on the third anniversary of the grant date.

(2) 125,000 of the options granted vest one-third upon the first anniversary of the grant date, one-third upon the second anniversary of the grant date and one-third upon the third anniversary of the grant date. 100,000 of the options granted vest upon the achievement of key clinical milestones for XBIO-101 and 25,000 of the options granted vest upon the achievement of key development milestones related to PSA.

(3) References restricted stock units ("RSUs") granted on October 26, 2017. Each RSU represents the right to receive one share of the Company's common stock upon settlement, as defined. The RSUs vest one-third upon the first anniversary of the grant date, one-third upon the second anniversary of the grant date and one-third upon the third anniversary of the grant date.

(4) Vests one-third upon the first anniversary of the grant date, one-third upon the second anniversary of the grant date and one-third upon the third anniversary of the grant date.

(5) Vested one-third upon March 3, 2015, one-third upon March 15, 2016 and one-third upon March 15, 2017.

(6) Vested one-third upon the first anniversary of the grant date, one-third upon the second anniversary of the grant date and one-third upon the third anniversary of the grant date.

(7) Vests one-third upon the first anniversary of the grant date, one-third upon the second anniversary of the grant date and one-third upon the third anniversary of the grant date.

Employment Agreements with our Named Executive Officers

Employment Agreement with Mr. Eisenberg

We entered into an employment agreement with Mr. Eisenberg effective as of December 1, 2016 for him to serve as Chief Operating Officer (the "Original Agreement"). The Original Agreement was for an initial term of one year, and automatically renewed for successive one year periods unless either party gave notice to the other no later than 90 days prior to the expiration of the then-applicable term; provided, however, that we could terminate the Original Agreement at any time. Mr. Eisenberg's annual salary under the Original Agreement was $300,000, and was subject to annual review and upward adjustment only by the Compensation Committee of the Board. Mr. Eisenberg was also eligible to receive a bonus equal to 35% of his annual salary based on the attainment of certain individual and/or Company goals established by the Board or a committee thereto. Mr. Eisenberg was also eligible to participate in our employee benefit, welfare and other plans, as may be maintained by us from time to time, on a basis no less favorable than those provided to other similarly situated executives of the Company. Mr. Eisenberg was also subject to certain customary confidentiality, non-solicitation and non-competition provisions.

Under the Original Agreement, if Mr. Eisenberg's employment was terminated by us without "Cause" (as defined in the Original Agreement) or if he resigned for "Good Reason" (as defined in the Original Agreement), he was entitled to receive (i) six months of his then current base salary, paid over time in accordance with our payroll practices then in effect if he had been employed by us for six months or less, (ii) 12 months of his then current base salary, paid over time in accordance with our payroll practices then in effect if he had been employed by us for more than six months, (iii) a pro-rated annual bonus and (iv) payment of premiums for continued health benefits under COBRA for up to six months.

On October 26, 2017, the Company amended and restated the Original Agreement in order to employ Mr. Eisenberg as the Chief Executive Officer of the Company, effective as of the same date (the "Amended Agreement"). The terms of the Amended Agreement were substantially similar to the terms of the Original Agreement, except that Mr. Eisenberg is now eligible to receive a bonus equal to 50% of his annual salary based on the attainment of certain individual and/or Company goals established by the Board or a committee thereto, and if Mr. Eisenberg's employment is terminated by us without "Cause" (as defined in the Amended Agreement) or if he resigns for "Good Reason" (as defined in the Amended Agreement), he will be entitled to receive (i) within thirty days following the date of termination, an amount equal to one times his then current base salary, (ii) a pro-rated annual bonus and (iii) payment of premiums for continued health benefits under COBRA for up to twelve months.

Employment Agreement with Mr. Parslow

We entered into an employment agreement with Mr. Parslow effective as of April 3, 2017 (the "Parslow Employment Agreement"). The Parslow Employment Agreement does not provide for a specified term of employment and Mr. Parslow's employment will be on an at-will basis. Mr. Parslow will receive an initial annual base salary of $265,000 and is eligible to earn an annual cash incentive bonus, which is initially set at a target aggregate bonus amount of 35% of Mr. Parslow's base salary, upon achievement of certain individual and/or Company performance goals set by the Compensation Committee. Mr. Parslow is also eligible to participate in the Company's employee benefit, welfare and other plans, as may be maintained by the Company from time to time, on a basis no less favorable than those provided to other similarly-situated executives of the Company. Mr. Parslow is also subject to certain customary confidentiality, non-solicitation and non-competition provisions.

If Mr. Parslow's employment is terminated by the Company without "cause" (as defined in the Parslow Employment Agreement) or Mr. Parslow resigns for "good reason" (as defined in the Parslow Employment Agreement), after six months of employment but before his first anniversary with the Company, he will be entitled to receive (i) six months of his then current base salary, paid over time in accordance with the Company's payroll practices then in effect and (ii) payment of premiums for continued health benefits under COBRA for up to six months. If Mr. Parslow's employment is terminated by the Company without "cause" (as defined in the Parslow Employment Agreement) or Mr. Parslow resigns for "good reason" (as defined in the Parslow Employment Agreement), after his first anniversary with the Company, he will be entitled to receive (i) one year of his then current base salary, paid over time in accordance with the Company's payroll practices then in effect and (ii) payment of premiums for continued health benefits under COBRA for up to one year.

Employment Agreement with Dr. Lockshin

We entered into an employment agreement with Dr. Lockshin effective as of January 1, 2017 (the "Lockshin Employment Agreement"). The Lockshin Employment Agreement does not provide for a specified term of employment and Dr. Lockshin's employment will be on an at-will basis. Dr. Lockshin will receive an initial annual base salary of $250,000 and is eligible to earn an annual performance-based cash incentive bonus, which is initially set at a target aggregate bonus amount of 35% of Dr. Lockshin's base salary, upon achievement of certain individual and/or Company performance goals established by the Board or a committee thereto. Dr. Lockshin is also eligible to participate in the Company's employee benefit, welfare and other plans, as may be maintained by the Company from time to time, on a basis no less favorable than those provided to other similarly-situated executives of the Company. Dr. Lockshin is also subject to certain customary confidentiality, non-solicitation and non-competition provisions.

If Dr. Lockshin's employment is terminated by the Company without "Cause" (as defined in the Lockshin Employment Agreement) or Dr. Lockshin terminates his employment for "Good Reason" (as defined in the Lockshin Employment Agreement) and Dr. Lockshin executes and does not revoke a general release of claims against the Company, then he will be entitled to receive (i) one year of his then current base salary, paid over time in accordance with the Company's payroll practices then in effect and (ii) payment of premiums for continued health benefits under COBRA for up to twelve months.

Potential Payments Upon Termination or Change of Control

Our named executive officers may be entitled to payments upon termination or change in control. The details of such payments are included in the description of their employment agreements above.

Director Compensation

Each of our non-employee, independent directors is currently entitled to receive an annual retainer of $50,000, payable in equal quarterly installments, an option to acquire 25,000 shares of the Company's common stock upon initial appointment to the Board, and an additional option to acquire 25,000 shares each year thereafter on the date of the Company's annual meeting of stockholders. All members of our board are reimbursed for their usual and customary expenses incurred in connection with their service on the Board, including out-of-pocket expenses, transportation, and airfare on the Company's business.

Director Compensation Table

As our employee director during fiscal 2018, Mr. Eisenberg did not receive any compensation for his Board service during the last completed year. The following table sets forth information for the year ended December 31, 2018 regarding the compensation awarded to, earned by or paid to our non-employee directors:

Name	Fees Earned or Paid in Cash ($)	Stock Awards ($)	Option Awards[1][2] ($)	All Other Compensation ($)	Total ($)
Dr. James E. Callaway	$ 50,000	–	$ 65,642	–	$ 115,642
Firdaus J. Dastoor	$ 50,000	–	$ 65,642	–	$ 115,642
Dr. Dmitry Genkin	$ –	–	$ –	–	$ –
Roman Knyazev	$ –	–	$ –	–	$ –
Dr. Roger Kornberg	$ 50,000	–	$ 65,642	–	$ 115,642
Mr. Adam Logal	$ 50,000	–	$ 65,642	–	$ 115,642

(1) The amounts represent the aggregate grant date fair value of stock options granted during 2018. For a discussion of the assumptions and methodology used to calculate the value of our stock options, see Note 10 to our audited financial statements included in Item 8 of the Original Filing.

(2) The table below shows the aggregate number of option awards outstanding for each of our non-employee directors as of December 31, 2018:

Name	Option Awards (#)
Dr. James Callaway	50,000
Firdaus J. Dastoor	95,455
Dr. Dmitry Genkin	37,879
Roman Knyazev	37,879
Dr. Roger Kornberg	75,000
Adam Logal	50,000

In addition to the option awards described above, Mr. Dastoor holds a warrant to purchase 48,485 shares of our common stock at $7.92 per share. These warrants are fully vested and expire in December 2019. In addition, Dr. Genkin holds a warrant to purchase 30,304 shares of our common stock at $13.86 per share. These warrants are fully vested and expire in April 2021.

See “Certain Relationships and Related Party Transactions” below for compensation arrangements involving specific members of the Board.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

During the fiscal year ended December 31, 2018 and the fiscal year ended December 31, 2017, there was not, nor is there any currently proposed transaction or series of similar transactions to which Xenetic was or is to be a party in which the amount involved exceeded or exceeds the lesser of $120,000 or 1% of the average of our total assets at year end for the last two completed fiscal years and in which any executive officer, director or holder of more than 5% of any class of voting securities of Xenetic and members of that person's immediate family had, has or will have a direct or indirect material interest, other than as set forth in "Executive Compensation" and "Director Compensation Table" above and disclosed below.

Policy Regarding Related Party Transactions

Our Board has adopted a written related party transaction policy to set forth the policies and procedures for the review and approval or ratification of related party transactions. Any transaction between the Company and its officers, directors, principal stockholders or affiliates is required to be on terms no less favorable to us than could be reasonably obtained in arms-length transactions with independent third-parties, and any such material related party transactions must also be reviewed and approved by a majority of the Board of Directors. All of the actions described in this section occurred prior to the adoption of this policy, except for the acquisition of the XCART Technology. On March 16, 2018, our Board formed the Strategic Alternatives Committee (the "SAC") to evaluate an alternative transaction and other strategic alternatives for the Company should they arise. James Callaway, an independent outside director of the Company, was appointed Chair of the SAC. The SAC had primary oversight over the XCART Technology acquisition.

PJSC Pharmsynthez

Pharmsynthez (formerly, OJSC Pharmsynthez) is our largest and controlling stockholder with a share ownership of 43.5% of the total issued and outstanding common stock at March 31, 2019. In addition to its common stock ownership, Pharmsynthez holds outstanding warrants to purchase our common stock and approximately 1.5 million shares of our issued and outstanding Series B Preferred Stock at March 31, 2019. Pharmsynthez was a related party of SynBio, which is related party of ours, and acquired 100% of SynBio in February 2017. The combined ownership of Pharmsynthez and SynBio was 51.4% at March 31, 2019. In addition, one of our directors, Dr. Dmitry Genkin, is the Executive Chairman of the board of directors of Pharmsynthez, a second director of ours, Mr. Roman Knyazev, is also a director of Pharmsynthez and one of our executive officers, Dr. Curtis Lockshin, is an officer of a wholly-owned subsidiary of Pharmsynthez. In November 2009, the Company entered into a collaborative research and development license agreement with Pharmsynthez (the "Pharmsynthez Arrangement") pursuant to which the Company granted an exclusive license to Pharmsynthez to develop, commercialize and market six drug candidates based on the Company's PolyXen and ImuXen technology in certain territories. In exchange, Pharmsynthez granted an exclusive license to the Company to use any 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.

SynBio LLC

SynBio is one of our largest stockholders and owns approximately 7.9% of our total issued and outstanding common stock as of March 31, 2019 and all of our outstanding Series A Preferred Stock. In 2017, SynBio became a wholly-owned subsidiary of Pharmsynthez.

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

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

Through December 31, 2018, 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, 2018 and 2017.

Serum Institute

Serum Institute owns approximately 6.0% of our total issued and outstanding common stock at March 31, 2019. In addition to its common stock ownership, Serum Institute holds outstanding warrants to purchase our common stock. One of our directors, Firdaus Jal Dastoor, is currently a Group Director in charge of Finance and Corporate Affairs and Company Secretary of Serum Institute. In August 2011, we entered into a collaborative research and development agreement with Serum Institute 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 the 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.

Through December 31, 2018, we continued to engage in research and development activities with no resultant commercial products. No royalty revenue or expense was recognized by us related to the Serum Institute arrangement during the years ended December 31, 2018 and 2017.

Director Fees and Consulting Services Agreement with Dr. Dmitry Genkin

Dr. Genkin provided research and consulting services to the Company, for which he was paid approximately $50,000 during the year ended December 31, 2017. The agreement was terminated on July 31, 2017 prior to Mr. Genkin being reappointed to the Board in August 2017.

XCART Technology

On March 1, 2019, we entered into the Transaction to acquire the XCART platform technology. The XCART technology, developed by The Institute in collaboration with the 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.

In connection with the Transaction, on March 1, 2019, we entered into a Share Purchase Agreement with Hesperix pursuant to which the Company will purchase all of the issued and outstanding shares of capital stock of Hesperix, as well as additional transaction documents. Dr. Dmitry Genkin, one of our directors, is a director and significant shareholder of Hesperix. In addition, in connection with the Transaction, the Company has agreed to repay a $150,000 loan that Dr. Genkin entered into with Hesperix.

In addition, and in connection with the Transaction, Hesperix entered into the Hesperix Assignment Agreement with 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 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. Dr. Dmitry Genkin, one of our directors, is the Executive Chairman of the board of directors of Pharmsynthez. A second director of ours, Mr. Roman Knyazev, is also a director of Pharmsynthez and one of our executive officers, Dr. Curtis Lockshin is an officer of a wholly-owned subsidiary of Pharmsynthez.

Concurrent with the Share Purchase Agreement, we also entered into the OPKO Assignment Agreement with OPKO pursuant to which the Company will acquire and accept all of OPKO's right, title and interest in an Intellectual Property License Agreement entered into between the Institute and OPKO related to the XCART technology. 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 total, we will issue 7.5 million shares of our common stock in the Transaction, including 4.875 million shares to be issued to the shareholders of Hesperix and 2.625 million shares of common stock to be issued in connection with the OPKO Assignment Agreement. The closing of the Transaction is subject to customary closing conditions as well as conditions regarding (i) the Company having adequate financing to fund its future working capital obligations following the closing and (ii) the Company obtaining necessary and appropriate stockholder approvals, evidencing among other matters, approval of the Share Purchase Agreement and the transactions contemplated thereunder, including the issuance of the Transaction Shares. Subject to the satisfaction of the closing conditions, the Transaction is expected to close in the first half of 2019.

Empery Asset Management

Empery Tax Efficient II, LP ("ETE II Fund"), Empery Asset Management, LP ("Empery Asset"), Ryan M. Lane, and Martin D. Hoe (collectively, "Empery Asset Management") own approximately 9.96% of our total issued and outstanding common stock at March 31, 2019. On March 5, 2019, Empery Asset Management purchased 1,040,000 shares of our common stock, as well as prefunded warrants to purchase 509,000 shares of our common stock resulting in net proceeds to the Company of $2.7 million. In addition to its common stock and prefunded warrant ownership, Empery Asset Management holds outstanding warrants to purchase our common stock.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table and footnotes set forth certain information known to us regarding beneficial ownership of our capital stock as of March 31, 2019 for:

- each person known by us to be the beneficial owner of more than 5% of our capital stock;
- our named executive officers;
- each of our directors; and
- all executive officers and directors as a group.

The number of shares beneficially owned by each entity, person, director or executive officer is determined in accordance with the rules of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under such rules, beneficial ownership includes any shares over which the individual has sole or shared voting power or investment power as well as any shares that the individual has the right to acquire within 60 days through the exercise of any stock option, warrants or other rights. Except as otherwise indicated, and subject to applicable community property laws, the persons named in the table have sole voting and investment power with respect to all shares of common stock held by that person or entity.

The percentage of shares beneficially owned is computed on the basis of 10,443,889 shares of our common stock outstanding as of March 31, 2019, on an as-converted basis. Shares of our common stock that a person has the right to acquire within 60 days after March 31, 2019 are deemed outstanding for purposes of computing the percentage ownership of the person or entity holding such rights, but are not deemed outstanding for purposes of computing the percentage ownership of any other person, except with respect to the percentage ownership of all directors and executive officers as a group. Unless otherwise indicated below, the address for each beneficial owner listed is c/o Xenetic Biosciences, Inc., at 40 Speen Street, Suite 102, Framingham, Massachusetts 01701.

Name of Beneficial Owner	Number of Shares Beneficially Owned[1]	Percentage Beneficially Owned	Percentage Beneficially Owned After Closing
Fiscal Year 2018 Named Executive Officers and Directors			
Jeffrey F. Eisenberg	213,233[2]	2.00%	
James Parslow	116,666[3]	1.10%	
Dr. Curtis Lockshin	146,365[4]	1.38%	
Dr. James E. Callaway	37,500[5]	*	
Firdaus J. Dastoor	131,440[6]	1.24%	
Dr. Dmitry Genkin[7]	70,732[8]	*	
Roman Knyazev[9]	37,879[10]	*	
Dr. Roger Kornberg	62,500[11]	*	
Adam Logal	37,500[12]	*	
All executive officers and directors as a group (9 persons)	853,815[13]	7.56%	
5% Current Stockholders			
PJSC Pharmsynthez[7] [9]	9,335,159[14]	64.77%	
Empery Asset Management	1,040,000[15]	9.96%	
Serum Institute of India Private Limited	891,607[16]	8.33%	

* Represents beneficial ownership of less than one percent (1%).

(1) Unless otherwise indicated below, this table is based upon corporate records, information supplied by officers, directors and, in the case of principal stockholders, information provided by our transfer agent.

(2) The total beneficial ownership consists of 196,566 shares issuable upon exercise of options that are exercisable within 60 days of March 31, 2019 and 16,667 of vested restricted stock units.

(3) The total beneficial ownership consists of 116,666 shares issuable upon exercise of options that are exercisable within 60 days of March 31, 2019.

(4) The total beneficial ownership consists of 146,365 shares issuable upon exercise of options that are exercisable within 60 days of March 31, 2019.

(5) The total beneficial ownership consists of 37,500 shares issuable upon exercise of options that are exercisable within 60 days of March 31, 2019.

(6) The total beneficial ownership consists of 131,440 shares issuable upon exercise of warrants and options that are exercisable within 60 days of March 31, 2019.

(7) Dr. Genkin is the Chairman of the Board of Directors of Pharmsynthez.

(8) The total beneficial ownership consists of 2,549 shares of common stock owned directly and 68,183 shares issuable upon exercise of warrants and options that are exercisable within 60 days of March 31, 2019.

(9) Mr. Knyazev is the Deputy Chairman of the Board of Directors of Pharmsynthez.

(10) The total beneficial ownership consists of 37,879 shares issuable upon exercise of options that are exercisable within 60 days of March 31, 2019.

(11) The total beneficial ownership consists of 62,500 shares issuable upon exercise of options that are exercisable within 60 days of March 31, 2019.

(12) The total beneficial ownership consists of 37,500 shares issuable upon exercise of options that are exercisable within 60 days of March 31, 2019.

(13) The total beneficial ownership consists of 2,549 shares of common stock owned directly, 834,599 shares issuable upon exercise of warrants and options that are exercisable within 60 days of March 31, 2019 and 16,667 shares of restricted stock units that are vested.

(14) The total beneficial ownership consists of 5,365,455 shares of common stock owned directly or indirectly through SynBio, 2,909,090 shares issuable upon the conversion of Series B Preferred Stock and 1,060,614 shares issuable upon exercise of warrants that are exercisable within 60 days of March 31, 2019. SynBio is a wholly-owned subsidiary of Pharmsynthez. Pharmsynthez may be deemed to have shared voting and shared dispositive power with respect to all the shares owned by SynBio and therefore, Pharmsynthez may be deemed to be the beneficial owner of such shares. The address of PJSC Pharmsynthez is Office Center IT Park, 25 Liter ZH, Krasnogo Kursanta St., St. Petersburg, 197110, Russia.

(15) The Company has reviewed the Schedule 13G jointly filed with the SEC on March 11, 2019 by Empery Tax Efficient II, LP (“ETE II Fund”), Empery Asset Management, LP (“Empery Asset”), Ryan M. Lane, and Martin D. Hoe (such joint filers, collectively, “Empery Asset Management”), reporting ownership of these shares as of March 5, 2019. According to the Schedule 13G, each of Empery Asset, Ryan M. Lane and Martin D. Hoe beneficially owned 1,040,000 shares of common stock with shared voting and shared dispositive power with respect to all such shares, which excludes, in each case, 509,000 shares of common stock issuable upon exercise of pre-funded warrants and 1,549,000 shares of common stock issuable upon exercise of warrants. Pursuant to the terms of the warrants, Empery Asset Management cannot exercise the warrants to the extent the reporting persons would beneficially own, after any such exercise, more than 4.99% of the outstanding shares of our common stock. Pursuant to the terms of the pre-funded warrants, Empery Asset Management cannot exercise the warrants to the extent the reporting persons would beneficially own, after any such exercise, more than 9.99% of the outstanding shares of our common stock. ETE II Fund beneficially owned 853,271 shares of common stock with shared voting and shared dispositive power with respect to all such shares, which excludes 417,611 shares of common stock issuable upon exercise of pre-funded warrants and 1,270,882 shares of common stock issuable upon exercise of warrants. ETE II Fund’s beneficial ownership is included within Empery Assets’ share ownership amounts reflected above. The address of Empery Asset Management is 1 Rockefeller Plaza, Suite 1205 New York, New York 10020.

(16) The total beneficial ownership consists of 631,000 shares of common stock owned directly and indirectly by related affiliates of Serum Institute of India Private Limited and 260,607 shares issuable upon exercise of warrants that are exercisable within 60 days of March 31, 2019. The address of Serum Institute of India is S. No. 212/2, Off Soli Poonawalla Road, Hadapsar, Pune, 411028, Maharashtra, India.

Equity Compensation Plan Information

The following table sets forth information as of December 31, 2018 with respect to compensation plans under which equity securities are authorized for issuance:

Plan Category	Number of Securities to be Issued upon Exercise of Outstanding Options, Warrants and Rights	Weighted Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans
Equity compensation plans approved by security holders	1,708,011[1]	$ 3.73	1,599,620
Equity compensation plans not approved by security holders	175,000[2]	4.57	–
Total	1,883,011	$ 3.80	1,599,620

(1) Consists of 1,708,011 shares of our common stock to be issued upon the exercise of outstanding stock options and restricted stock units under the Xenetic Biosciences, Inc. Amended and Restated 2014 Equity Incentive Plan.

(2) Represents inducement award granted in 2017 that was not covered under the Xenetic Biosciences, Inc. Amended and Restated 2014 Equity Incentive Plan.

DESCRIPTION OF CAPITAL STOCK

The following is a summary of the rights and preferences of our capital stock. While we believe that the following description covers the material terms of our capital stock, the description may not contain all of the information that is important to you. We encourage you to read carefully this entire prospectus, any future related certificates of designation relating to the securities, as applicable, our articles of incorporation, as amended and the Bylaws and the other documents we refer to for a more complete understanding of our capital stock. Copies of our charter and bylaws are incorporated by reference as exhibits to the registration statement of which this Registration Statement is a part. See "Where You Can Find More Information."

General

Our charter provides that we may issue up to 45,454,546 shares of Common Stock, $0.001 par value per share, 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 May 6, 2019, there were issued and outstanding: 10,443,889 shares of Common Stock, 970,000 shares of Series A Preferred Stock, 1,804,394 shares of Series B Preferred Stock and 5,749,427 shares of Common Stock issuable upon exercise of warrants. Under Nevada law, stockholders are not generally liable for our debts or obligations.

Shares of Common Stock

Voting Rights

Our 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 the Series B 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.

Shares of Preferred Stock

The following description sets forth general terms and provisions of the preferred stock to which any prospectus supplement may relate. The statements below describing the preferred stock are in all respects subject to and qualified in their entirety by reference to our charter, bylaws, and any certificate of designation, designating terms of a series of preferred stock. The outstanding shares of our preferred stock have been validly issued, fully paid, and non-assessable. Because our board of directors has the power to establish the preferences, powers and rights of each series of preferred stock, our board of directors may afford the holders of any series of preferred stock preferences, powers and rights, voting or otherwise, senior to the rights of our common stockholders. The issuance of our preferred stock could adversely affect the voting power of holders of Common Stock and the likelihood that such holders will receive dividend payments and payments upon a liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change of control of the Company or other corporate action.

The rights, preferences, privileges and restrictions of our outstanding series of preferred stock are, and of each additional series of preferred stock, when and if issued in the future will be, fixed by the certificate of designation relating to the series. A prospectus supplement, relating to each series, will specify the terms of the preferred stock, as follows:

- the title and stated value of the preferred stock;
- the voting rights of the preferred stock, if applicable;
- the preemptive rights of the preferred stock, if applicable;
- the restrictions on alienability of the preferred stock, if applicable;
- the number of shares offered, the liquidation preference per share and the offering price of the shares;
- liability to further calls or assessment of the preferred stock, if applicable;
- the dividend rate(s), period(s) and payment date(s) or method(s) of calculation applicable to the preferred stock;
- the date from which dividends on the preferred stock will accumulate, if applicable;
- the procedures for any auction and remarketing for the preferred stock, if any;
- the provision for a sinking fund, if any, for the preferred stock;
- the provision for and any restriction on redemption, if applicable, of the preferred stock;
- the provision for and any restriction on repurchase, if applicable, of the preferred stock;
- any listing of the preferred stock on any securities exchange;
- the terms and provisions, if any, upon which the preferred stock will be convertible into Common Stock, including the conversion price (or manner of calculation) and conversion period;
- the terms under which the rights of the preferred stock may be modified, if applicable;
- any other specific terms, preferences, rights, limitations or restrictions of the preferred stock;
- a discussion of certain material federal income tax considerations applicable to the preferred stock;
- the relative ranking and preferences of the preferred stock as to dividend rights and rights upon the liquidation, dissolution or winding-up of our affairs;
- any limitation on issuance of any series of preferred stock ranking senior to or on a parity with the series of preferred stock as to dividend rights and rights upon the liquidation, dissolution or winding-up of our affairs; and
- any limitations on direct or beneficial ownership and restrictions on transfer of the preferred stock.

Transfer Agent and Registrar

The transfer agent and registrar for our Common Stock and preferred stock is Empire Stock Transfer, Inc.

Restrictions on Transfer

Transfers of shares of capital stock of the Company shall be made only (i) by entering upon the stock-transfer books of the Company or (ii) by transfer agents designated to transfer shares of capital stock of the Company.

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.

Anti-Takeover Effects

Certain provisions of Xenetic's Articles of Incorporation, Bylaws, and 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 Articles of Incorporation, the issuance of Blank Check Preferred Stock with preferences, limitations and relative rights determined by a corporation's board of directors without stockholder approval.

Xenetic's Articles of Incorporation 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.

Xenetic 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.

Stock Exchange Listing

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

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, a very limited public market exists for our common stock. Future sales of our Common Stock in the public market, or the availability of such shares for sale in the public market, could adversely affect market prices prevailing from time to time. As described below, approximately [●]% of our Common Stock outstanding immediately after this offering will be subject to contractual and legal restrictions on resale. Nevertheless, sales of our Common Stock eligible for sale in the public market immediately after this offering, or sales of other shares eligible for sale after such restrictions lapse, or the perception that those sales may occur, could adversely affect the prevailing market price at such time and our ability to raise equity capital in the future.

Based on the number of shares outstanding as of [●], 2019, upon the closing of this offering and assuming no exercise of the underwriters' option to purchase additional shares, [●] shares of Common Stock will be outstanding, assuming no outstanding options or warrants are exercised. All of the shares of common stock sold in this offering will be freely tradable without restrictions or further registration under the Securities Act, except for any shares sold to our "affiliates," as that term is defined under Rule 144 under the Securities Act. Of the remaining [●] shares of Common Stock held by existing stockholders, [●] shares are "restricted securities," as that term is defined in Rule 144 under the Securities Act. Restricted securities may be sold in the public market only if registered or if their resale qualifies for exemption from registration described pursuant to Rule 144 promulgated under the Securities Act.

As a result of the lock-up agreements referred to below and the provisions of Rule 144 under the Securities Act, the shares of our Common Stock (excluding the shares sold in this offering) that will be available for sale in the public market are as follows:

Number of Shares and % of Total Outstanding	Date Available for Sale into Public Market
shares, or %	On the date of this prospectus.
shares, or %	[●] days after the date of this prospectus, due to lock-up agreements between the holders of these shares and the underwriters. However, the representatives of the underwriters, acting together, can waive the provisions of these lock-up agreements and allow these stockholders to sell their shares at any time.
shares, or %	, 2019, due to the restrictions subject to Rule 144.

Lock-up Agreements

In connection with this offering, we, our directors, our executive officers and certain major holders of substantially all of our shares of Common Stock outstanding as of [●], 2019 have agreed, subject to certain exceptions, with the underwriters not to dispose of or hedge any shares of our Common Stock or securities convertible into or exchangeable for shares of Common Stock during the period from the date of the lock-up agreement continuing through the date [●] days after the date of this prospectus, except with the prior written consent of the representative of the underwriters, and certain other exceptions. The representative of the underwriters has advised us that it has no current intent or arrangement to release any of the shares subject to the lock-up agreements prior to the expiration of the lock-up period.

UNDERWRITING

Maxim Group LLC is acting as sole bookrunner and as representative of the underwriters (the "Representative"). Subject to the terms and conditions of an underwriting agreement between us and the Representative, we have agreed to sell to each underwriter named below, and each underwriter named below has severally agreed to purchase, at the public offering price less the underwriting discounts set forth on the cover page of this prospectus, the number of shares of common stock listed next to its name in the following table:

Name of Underwriter	Number of Shares
Maxim Group LLC	
Total	

The underwriters are committed to purchase all the shares of common stock offered by this prospectus if they purchase any shares of common stock. The underwriting agreement also provides that if an underwriter defaults, the purchase commitments of non-defaulting underwriters may be increased or the offering may be terminated. The underwriters are not obligated to purchase the shares of common stock covered by the underwriters' over-allotment option described below. The underwriters are offering the shares of common stock, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel, and other conditions contained in the underwriting agreement, such as the receipt by the underwriters of officer's certificates and legal opinions. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

Over-Allotment Option

We have granted to the underwriters an option, exercisable no later than 45 calendar days after the date of the underwriting agreement, to purchase up to _____ shares of common stock at the public offering price listed on the cover page of this prospectus, less underwriting discounts and commissions. The underwriters may exercise this option only to cover over-allotments, if any, made in connection with this offering. To the extent the option is exercised and the conditions of the underwriting agreement are satisfied, we will be obligated to sell to the underwriters, and the underwriters will be obligated to purchase, these additional shares of common stock.

Discounts and Commissions

We have agreed to pay the underwriters (i) a cash fee equal to seven percent (7.0%) of the aggregate gross proceeds.

The Representative has advised us that the underwriters propose to offer the shares directly to the public at the public offering price set forth on the cover of this prospectus. In addition, the representative may offer some of the shares to other securities dealers at such price less a concession of up to $_____ per share. After the offering to the public, the offering price and other selling terms may be changed by the Representative without changing the Company's proceeds from the underwriters' purchase of the shares.

The following table summarizes the public offering price, underwriting commissions and proceeds before expenses to us assuming both no exercise and full exercise of the underwriters' option to purchase additional shares. The underwriting commissions are equal to the public offering price per share less the amount per share the underwriters pay us for the shares.

	Per Share	Total Without Over Allotment	Total With Over Allotment
Public offering price	$		
Underwriting discounts and commissions	$		
Proceeds, before expenses, to us	$		

We estimate that the total expenses of the offering, including registration, filing and listing fees, printing fees and legal and accounting expenses, but excluding underwriting discounts and commissions, will be approximately $[ ], all of which are payable by us. This figure includes expense reimbursements we have agreed to pay Maxim for reimbursement of its expenses related to the offering up to a maximum aggregate expense allowance of $_____, for which we have paid a $[*] advance, which will be returned to us to the extent not offset by actual expenses.

Lock-Up Agreements

We and each of our officers, directors, affiliates and certain existing stockholders aggregating at least [•] of our outstanding shares have agreed, subject to certain exceptions, not to offer, issue, sell, contract to sell, encumber, grant any option for the sale of or otherwise dispose of any shares of our common stock or other securities convertible into or exercisable or exchangeable for shares of our common stock for a period of six (6) months after this offering is completed without the prior written consent of Maxim Group LLC.

Maxim Group LLC may in its sole discretion and at any time without notice release some or all of the shares subject to lock-up agreements prior to the expiration of the lock-up period. When determining whether or not to release shares from the lock-up agreements, the representative will consider, among other factors, the security holder's reasons for requesting the release, the number of shares for which the release is being requested and market conditions at the time.

Right of First Refusal

We have granted the Representative a right of first refusal, for a period of nine months from the commencement of sales of this offering, to act as sole and exclusive investment banker, book-runner, financial advisor, underwriter and/or placement agent, at the Representative's sole and exclusive discretion, for each and every future public and private equity and debt offering, including all equity linked financings (each, a "Subject Transaction"), during such nine (9) month period, of the Company, or any successor to or subsidiary of the Company, on terms and conditions customary to the Representative for such Subject Transactions. The right of first referral does not apply to any financing or transactions consummated without the retention of a Financial Industry Regulatory Authority ("FINRA") registered broker dealer or other party to which the Company pays a finder's fee.

Indemnification

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, and to contribute to payments that the underwriters may be required to make for these liabilities.

Price Stabilization, Short Positions, and Penalty Bids

In connection with this offering, the underwriters may engage in transactions that stabilize, maintain or otherwise affect the price of our common stock. Specifically, the underwriters may over-allot in connection with this offering by selling more shares than are set forth on the cover page of this prospectus. This creates a short position in our common stock for its own account. The short position may be either a covered short position or a naked short position. In a covered short position, the number of shares common stock over-allotted by the underwriters is not greater than the number of shares of common stock that they may purchase in the over-allotment option. In a naked short position, the number of shares of common stock involved is greater than the number of shares common stock in the over-allotment option. To close out a short position, the underwriters may elect to exercise all or part of the over-allotment option. The underwriters may also elect to stabilize the price of our common stock or reduce any short position by bidding for, and purchasing, common stock in the open market.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter or dealer repays selling concessions allowed to it for distributing a security in this offering because the underwriter repurchases that security in stabilizing or short covering transactions.

Finally, the underwriters may bid for, and purchase, shares of our common stock in market making transactions, including "passive" market making transactions as described below.

These activities may stabilize or maintain the market price of our common stock at a price that is higher than the price that might otherwise exist in the absence of these activities. The underwriters are not required to engage in these activities, and may discontinue any of these activities at any time without notice.

In connection with this offering, the underwriters and selling group members, if any, or their affiliates may engage in passive market making transactions in our common stock immediately prior to the commencement of sales in this offering, in accordance with Rule 103 of Regulation M under the Exchange Act. Rule 103 generally provides that:

- a passive market maker may not effect transactions or display bids for our common stock in excess of the highest independent bid price by persons who are not passive market makers;
- net purchases by a passive market maker on each day are generally limited to 30% of the passive market maker's average daily trading volume in our common stock during a specified two-month prior period or 200 shares, whichever is greater, and must be discontinued when that limit is reached; and
- passive market making bids must be identified as such.

Electronic Distribution

A prospectus in electronic format may be made available on a website maintained by the representatives of the underwriters and may also be made available on a website maintained by other underwriters. The underwriters may agree to allocate a number of shares to underwriters for sale to their online brokerage account holders. Internet distributions will be allocated by the representatives of the underwriters to underwriters that may make Internet distributions on the same basis as other allocations. In connection with the offering, the underwriters or syndicate members may distribute prospectuses electronically. No forms of electronic prospectus other than prospectuses that are printable as Adobe® PDF will be used in connection with this offering.

The underwriters have informed us that they do not expect to confirm sales of shares offered by this prospectus to accounts over which they exercise discretionary authority.

Other than the prospectus in electronic format, the information on any underwriter's website and any information contained in any other website maintained by an underwriter is not part of the prospectus or the registration statement of which this prospectus forms a part, has not been approved and/or endorsed by us or any underwriter in its capacity as underwriter and should not be relied upon by investors.

Certain Relationships

Certain of the underwriters and their affiliates may provide, from time to time, investment banking and financial advisory services to us in the ordinary course of business, for which they may receive customary fees and commissions.

LEGAL MATTERS

Westward Law, LLC, Las Vegas, Nevada, will pass upon the validity of the Xenetic Common Stock offered by this Registration Statement. Certain legal matters in connection with this offering will be passed upon for the underwriters by Ellenoff Grossman & Schole LLP, New York, New York.

EXPERTS

The financial statements of Xenetic Biosciences, Inc. as of December 31, 2018 and 2017, and for each of the years in the two-year period ended December 31, 2018, have been included herein and in the registration statement in reliance upon the report of Marcum LLP, independent registered public accounting firm, appearing elsewhere herein, and upon the authority of said firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

Xenetic files annual, quarterly and special reports, proxy statements and other information with the SEC. Xenetic's SEC filings are available to the public from commercial document retrieval services and on the website maintained by the SEC at http://www.sec.gov. 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 www.xeneticbio.com as soon as practicable after we electronically file such forms, or furnish them to, the SEC.

We are subject to the informational and reporting requirements of the Securities Exchange Act of 1934, as amended, and have filed and will file annual, quarterly and current reports, proxy statements and other information with the SEC. You can read our SEC filings, including the registration statement, over the Internet at the SEC's website (http://www.sec.gov). You may also read and copy any document we file with the SEC at its public reference facility at 100 F Street, N.E., Room 1580, Washington, D.C. 20549.

Xenetic has supplied all information contained in this Prospectus relating to Xenetic. If you would like to request documents from Xenetic please send a request in writing or by telephone to the following address:

Xenetic Biosciences, Inc.
40 Speen Street, Suite 102
Framingham, Massachusetts 01701
Telephone: (781) 778-7720
Attn: Corporate Secretary

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XENETIC BIOSCIENCES, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

	March 31, 2019 (Unaudited)	December 31, 2018
ASSETS		
Current assets:		
Cash	$ 2,018,133	$ 571,605
Restricted cash	66,510	66,510
Prepaid expenses and other	1,116,758	555,856
Total current assets	3,201,401	1,193,971
Property and equipment, net	3,498	4,956
Goodwill	3,283,379	3,283,379
Indefinite-lived intangible assets	9,243,128	9,243,128
Other assets	724,786	705,660
Total assets	$ 16,456,192	$ 14,431,094
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,040,289	$ 934,147
Accrued expenses and other current liabilities	965,738	665,641
Total current liabilities	2,006,027	1,599,788
Deferred tax liability	2,918,518	2,918,518
Other liabilities	13,119	–
Total liabilities	$ 4,937,664	$ 4,518,306
Commitments (Note 11)		
Stockholders' equity:		
Preferred stock, 10,000,000 shares authorized		
Series B, $0.001 par value: 1,804,394 shares issued and outstanding as of March 31, 2019 and December 31, 2018	1,804	1,804
Series A, $0.001 par value: 970,000 shares issued and outstanding as of March 31, 2019 and December 31, 2018	970	970
Common stock, $0.001 par value; 45,454,546 shares authorized as of March 31, 2019 and December 31, 2018; 10,767,774 and 9,727,774 shares issued as of March 31, 2019 and December 31, 2018, respectively; 10,443,889 and 9,403,889 shares outstanding as of March 31, 2019 and December 31, 2018, respectively	10,766	9,726
Additional paid in capital	171,093,279	168,161,329
Accumulated deficit	(154,560,845)	(153,233,595)
Accumulated other comprehensive income	253,734	253,734
Treasury stock	(5,281,180)	(5,281,180)
Total stockholders' equity	11,518,528	9,912,788
Total liabilities and stockholders' equity	$ 16,456,192	$ 14,431,094

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

XENETIC BIOSCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended March 31,	
	2019	**2018**
Operating costs and expenses:		
Research and development	$ (463,782)	$ (706,271)
General and administrative	(863,373)	(1,122,072)
Loss from operations	(1,327,155)	(1,828,343)
Other income (expense):		
Other income (expense)	(245)	5,398
Interest income	150	427
Total other income (expense)	(95)	5,825
Net loss	$ (1,327,250)	$ (1,822,518)
Deemed dividend	(3,879,447)	–
Net loss applicable to common stockholders	$ (5,206,697)	$ (1,822,518)
Basic and diluted loss per share	$ (0.54)	$ (0.21)
Weighted-average shares of common stock outstanding, basic and diluted	9,681,222	8,717,541

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

XENETIC BIOSCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(Unaudited)

THREE MONTHS ENDED MARCH 31, 2019

	Preferred Stock		Common Stock						
	Number of Shares	Par Value ($0.001)	Number of Shares	Par Value ($0.001)	Additional Paid in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Treasury Stock	Total Stockholders' Equity
Balance as of January 1, 2019	2,774,394	$ 2,774	9,727,774	$ 9,726	$ 168,161,329	$ (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	–	–	1,040,000	1,040	2,698,010	–	–	–	2,699,050
Deemed dividend related to Series B Preferred Stock down round provision	–	–	–	–	3,879,447	–	–	–	3,879,447
Accretion of deemed dividend related to Series B Preferred Stock down round provision	–	–	–	–	(3,879,447)	–	–	–	(3,879,447)
Share-based expense	–	–	–	–	243,089	–	–	–	243,089
Common stock awards to vendors	–	–	–	–	17,427	–	–	–	17,427
Warrant revaluation	–	–	–	–	(26,576)	–	–	–	(26,576)
Net loss	–	–	–	–	–	(1,327,250)	–	–	(1,327,250)
Balance as of March 31, 2019	2,774,394	$ 2,774	10,767,774	$ 10,766	$ 171,093,279	$ (154,560,845)	$ 253,734	$ (5,281,180)	$ 11,518,528

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

XENETIC BIOSCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(Unaudited)

THREE MONTHS ENDED MARCH 31, 2018

	Preferred Stock		Common Stock						
	Number of Shares	Par Value ($0.001)	Number of Shares	Par Value ($0.001)	Additional Paid in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Treasury Stock	Total Stockholders' Equity
Balance as of January 1, 2018	3,090,742	$ 3,090	9,041,426	$ 9,040	$ 165,249,912	$ (145,933,137)	$ 253,734	$ (5,281,180)	$ 14,301,459
Share-based expense	–	–	–	–	383,850	–	–	–	383,850
Common stock awards to vendors	–	–	–	–	17,427	–	–	–	17,427
Warrant expense	–	–	–	–	4,917	–	–	–	4,917
Net loss	–	–	–	–	–	(1,822,518)	–	–	(1,822,518)
Balance as of March 31, 2018	3,090,742	$ 3,090	9,041,426	$ 9,040	$ 165,656,106	$ (147,755,655)	$ 253,734	$ (5,281,180)	$ 12,885,135

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

XENETIC BIOSCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)

	Three Months Ended March 31,	
	2019	**2018**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (1,327,250)	$ (1,822,518)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	1,458	5,723
Gain on sale of property and equipment	(2,000)	–
Share-based expense	243,089	383,850
Warrant-based (income) expense for services	(26,576)	4,917
Vendor share-based expense	17,427	17,427
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(536,698)	(51,888)
Accounts payable, accrued expenses and other liabilities	376,028	(204,314)
Net cash used in operating activities	(1,254,522)	(1,666,803)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceeds from sale of property and equipment	2,000	–
Net cash provided by investing activities	2,000	–
CASH FLOWS FROM FINANCING ACTIVITIES:		
Net proceeds from issuance of common stock and warrants	2,699,050	–
Net cash provided by financing activities	2,699,050	–
Net change in cash and restricted cash	1,446,528	(1,666,803)
Cash and restricted cash at beginning of period	638,115	5,599,572
Cash and restricted cash at end of period	$ 2,084,643	$ 3,932,769
SUPPLEMENTAL CASH FLOW INFORMATION:		
Cash paid for interest	$ 8	$ 671
SUPPLEMENTAL SCHEDULE OF NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Right of use asset acquired in exchange for lease liability	$ 43,330	$ –

The accompanying notes are an integral part of these unaudited condensed 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 the discovery, research and development of next-generation biologic drugs and novel oncology therapeutics. Xenetic's most advanced investigational drug candidate is oncology therapeutic XBIO-101 (sodium cridanimod) for the treatment of progestin – resistant endometrial cancer. Xenetic's lead proprietary technology is PolyXen™, 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.

On March 1, 2019, the Company entered into an agreement to acquire the novel Chimeric Antigen Receptor ("CAR") T cell platform technology, referred to herein as "XCART" (the "Transaction") a proximity-based screening platform capable of identifying CAR constructs that can target patient-specific tumor neoantigens, with a demonstrated proof of mechanism in B-cell Non-Hodgkin 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. The closing of the Transaction is subject to customary closing conditions as well as conditions regarding (i) the Company having adequate financing to fund its future working capital obligations following the closing and (ii) the Company obtaining necessary and appropriate stockholder approvals, evidencing among other matters, approval of the Share Purchase Agreement and the transactions contemplated thereunder, including the issuance of the transaction shares. Subject to the satisfaction of the closing conditions, the Transaction is expected to close in the first half of 2019.

As used in this Quarterly Report on Form 10-Q ("Quarterly Report"), unless otherwise indicated, all references herein to "Xenetic," the "Company," "we" or "us" refer to Xenetic Biosciences, Inc. and its wholly owned subsidiaries.

The Company, directly or indirectly, through its wholly-owned subsidiary, 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 U.S. federal trademark registrations and applications, and unregistered trademarks and service marks, including but not limited to Virexxa®, OncoHist™, PolyXen™, ErepoXen™, ImuXen™, and PulmoXen™, which are used throughout this Quarterly 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

The Company incurred a net loss of approximately $1.3 million for the three months ended March 31, 2019. The Company had an accumulated deficit of approximately $154.6 million as of March 31, 2019 as compared to an accumulated deficit of approximately $153.2 million at December 31, 2018. Working capital (deficit) was approximately $1.2 million and $(0.4) million at March 31, 2019 and December 31, 2018, respectively. The Company expects to continue incurring losses for the foreseeable future and will need to raise additional capital or pursue other strategic alternatives in the very near term in order to continue the pursuit of its business plan and continue as a going concern.

The Company believes that it has access to capital resources through possible public or private equity offerings, debt financings, corporate collaborations, related party funding, or other means. On March 7, 2019, the Company closed a $3.1 million in a registered direct common stock offering resulting in $2.7 million of net proceeds to the Company. However, the Company has not secured any commitment for additional financing at this time. The terms, timing and extent of any future financing will depend upon several factors, including the achievement of progress in the Company's clinical development programs, the Company's 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 the Company's control.

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

2. Summary of Significant Accounting Policies

Preparation of Interim Financial Statements

The accompanying condensed consolidated financial statements were prepared by the Company pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC") and, in the opinion of management, include all normal and recurring adjustments necessary to present fairly the results of the interim periods shown. Certain information and footnote disclosures normally included in financial statements prepared in accordance with U.S. generally accepted accounting principles have been condensed or omitted pursuant to such SEC rules and regulations. Management believes that the disclosures made are adequate to make the information presented not misleading. The results for the interim periods are not necessarily indicative of results for the full year. The condensed consolidated financial statements contained herein should be read in conjunction with the consolidated financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2018 filed with the SEC on March 29, 2019 as amended on April 30, 2019.

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

Principles of Consolidation

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

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.

For the three months ended March 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.

Recently Adopted Accounting Standards

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 condensed consolidated financial statements.

In January 2017, the FASB issued ASU 2017-04: *Intangibles — Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment* that eliminated the requirement to calculate implied fair value of goodwill to measure a goodwill impairment charge. Instead, the new guidance requires entities to take an impairment charge based on the excess of a reporting unit's carrying amount over its fair value. The guidance is effective for the Company no later than 2020. The Company adopted ASU 2017-04 in the first quarter of fiscal 2019. Adoption of this standard did not have a material impact on the Company's condensed consolidated financial statements.

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 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 condensed consolidated financial statements, resulted in an approximate $40,000 increase in total assets and total liabilities in our condensed consolidated balance sheet and did not have any effect on accumulated deficit at the beginning of 2019. See Note 11 for further information

3. Significant Strategic Drug Development Collaborations – Related Parties

The Company has entered into various research, development, license and supply agreements with Takeda Pharmaceuticals Co. Ltd., Serum Institute of India ("Serum Institute"), its controlling stockholder PJSC Pharmsynthez ("Pharmsynthez") and SynBio LLC ("SynBio"), a wholly owned subsidiary of Pharmsynthez. The Company and its collaborative partners continue to engage in research and development activities with no resultant commercial products through March 31, 2019. No amounts were recognized as revenue related to these agreements during the three months ended March 31, 2019 or 2018.

4. Acquisitions

On March 1, 2019 (the "Signing Date"), the Company entered into the Share Purchase Agreement with Hesperix S.A., a Swiss Corporation ("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 will purchase from Sellers all of the issued and outstanding shares of capital stock of Hesperix.

Under the terms of the Share Purchase Agreement, the Company will issue to Sellers an aggregate of Four Million Eight Hundred Seventy-Five Thousand (4,875,000) shares of the Company's common stock (the "Transaction Shares"), regardless of the trading price per share of the Company's common stock 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 expects to issue the Transaction Shares pursuant to a registration statement on Form S-4.

The closing of the Transaction is subject to customary closing conditions as well as conditions regarding (i) the Company having adequate financing to fund its future working capital obligations following the closing and (ii) the Company obtaining necessary and appropriate stockholder approvals, evidencing among other matters, approval of the Share Purchase Agreement and the transactions contemplated thereunder, including the issuance of the Transaction Shares. Subject to the satisfaction of the closing conditions, the Transaction is expected to close in the first half of 2019. The Transaction is expected to be accounted for as an asset acquisition and, as a result, $0.5 million of costs related to the acquisition have been capitalized to date and are reflected in prepaid expenses and other in the condensed consolidated balance sheet.

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 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 (the "OPKO Assignment Agreement") with OPKO Pharmaceuticals, LLC ("OPKO"), 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 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 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 will issue One Million Nine Hundred Sixty-Eight Thousand Seven Hundred Fifty (1,968,750) shares of the Company's common stock to OPKO and Six Hundred Fifty-Six Thousand Two Hundred Fifty (656,250) shares of the Company's common stock to the Institute regardless of the trading price per share of the Company's common stock 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.

5. Property and Equipment, net

Property and equipment, net consists of the following:

	March 31, 2019	December 31, 2018
Office and computer equipment	$ 42,288	$ 42,289
Leasehold improvements	–	26,841
Furniture and fixtures	14,738	20,263
Property and equipment – at cost	57,026	89,393
Less accumulated depreciation	(53,528)	(84,437)
Property and equipment – net	$ 3,498	$ 4,956

Depreciation expense was approximately $1,000 and $6,000 for the three months ended March 31, 2019 and 2018, respectively.

6. Indefinite-Lived Intangible Assets

The Company's indefinite-lived intangible asset, OncoHist, is in-process research and development relating to the Company's business combination with SymbioTec in 2012. The carrying value of OncoHist was approximately $9.2 million as of March 31, 2019 and December 31, 2018, respectively. No impairment was recorded during the three months ended March 31, 2019 nor during the year ended December 31, 2018. OncoHist is not yet commercialized and, therefore, has not yet begun to be amortized as of March 31, 2019.

7. Fair Value Measurements

Accounting Standards Codification ("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 amounts of certain of the Company's financial instruments approximates fair value due to their short maturities. There were no financial instruments classified as Level 3 in the fair value hierarchy during the three months ended March 31, 2019 and March 31, 2018, respectively.

8. Stockholders' Equity

Common Stock

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) 1,040,000 shares of common stock, par value $0.001 per share and (ii) prefunded warrants to purchase 509,000 shares of common stock. The prefunded warrants were exercisable beginning on March 7, 2019 at an exercise price of $0.001 per share. The shares were sold at a price of $2.00 per share and the prefunded warrants were sold at a price of $1.999 per prefunded warrant, which represents the per share purchase price for the shares less the $0.001 per share exercise price for each such prefunded warrant. The holders of the prefunded warrants will 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 $2.25 per share, are 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 $1.90 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.

Series B Preferred Stock

As of March 31, 2019 and December 31, 2018 there were approximately 1.8 million shares of Series B Preferred Stock issued and outstanding which are convertible into Common Stock on a two-for-one basis. The 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 the three months ended March 31, 2019. There were no Series B Preferred Stock conversions during the three months ended March 31, 2019.

Warrants

In addition to the warrants issued in the registered direct offering, the Company has outstanding warrants to purchase an aggregate of 3,152,225 shares of common stock issued in connection with debt and equity financing arrangements as of March 31, 2019 at a weighted average exercise price of $4.30 and expiration dates ranging from July 2020 through November 2021.

No warrants were exercised during the three months ended March 31, 2019 and no warrants were granted or exercised during the three months ended March 31, 2018, respectively.

9. Share-Based Expense

Total share-based expenses related to stock options, restricted stock units ("RSUs"), common stock awards, and non-financing warrants were approximately $0.2 million and $0.4 million during the three months ended March 31, 2019 and 2018, respectively.

Share-based expenses is classified in the condensed consolidated statements of operations as follows:

	Three Months Ended March 31,	
	2019	2018
Research and development expenses	$ 11,418	$ 60,345
General and administrative expenses	222,522	345,849
	$ 233,940	$ 406,194

Employee Stock Options

No employee stock options or RSUs were granted nor exercised during the three months ended March 31, 2019 and 2018, respectively. The Company recognized a total of $0.2 million and $0.4 million of compensation expense related to employee stock options during the three months ended March 31, 2019 and 2018 respectively.

Non-Employee Stock Options

The Company did not grant any non-employee stock options during the three-months ended March 31, 2019. During the three months ended March 31, 2018, the Company granted 10,000 non-employee stock options. The Company recognized approximately $0 and $9,000 of expense related to non-employee stock options during the three months ended March 31, 2019 and 2018, respectively.

Common Stock Awards

During the three months ended March 31, 2019 and 2018, the Company granted 8,219 and 8,094 common stock awards, respectively, based on the value of the professional services provided and the average stock price during each respective quarter. As all services were rendered in each respective quarter, approximately $17,000 of expense related to common stock awards was recognized during each of the three-month periods ended March 31, 2019 and 2018, respectively. All common stock awards were authorized but not issued as of March 31, 2019.

Warrants

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 March 31, 2019 and December 31, 2018, warrants to purchase 539,202 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. The Company recognized income of approximately $27,000 as a result of a reduction in estimated fair value of warrants for the three months ended March 31, 2019. During the three months ended March 31, 2018, the Company recognized approximately $5,000 of expense on revaluation of warrants. No warrants were granted or exercised in connection with collaboration or consulting services during the three months ended March 31, 2019 and 2018. These warrants have an average weighted exercise price of $10.41 and expiration dates ranging from December 2019 through May 2021.

10. Income Taxes

During the three months ended March 31, 2019 and 2018, there was no provision for income taxes as the Company incurred losses during both periods. 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. The Company records a valuation allowance against its deferred tax assets as the Company believes it is more likely than not the deferred tax assets will not be realized. The valuation allowance against deferred tax assets was approximately $23.8 million and $23.5 million as of March 31, 2019 and December 31, 2018, respectively.

As of March 31, 2019, and December 31, 2018, the net deferred tax liability of $2.9 million on the condensed consolidated balance sheets is related to book and tax basis differences for intangible assets with indefinite lives that were acquired in the Company's January 2012 acquisition of SymbioTec. In accordance with ASC 740-10-30-18, the deferred tax liability related to the intangible assets cannot be used to offset deferred tax assets when determining the amount of the valuation allowance for deferred tax assets which are not more-likely-than-not to be realized. This results in a net deferred tax liability, even though the Company has a full valuation allowance on its other net deferred tax assets. This net deferred tax liability will continue to be reflected on the balance sheet until the related intangible assets are no longer held by the Company.

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

11. Commitments

Leases

The Company determines whether an arrangement is a lease at inception. On January 25, 2019, the Company relocated its corporate headquarters from Lexington Massachusetts to Framingham, Massachusetts. The sublease calls for total future minimum rent payments of approximately $50,000 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 condensed consolidated balance sheet. The Company recognized a ROU asset and a lease liability of approximately $43,000 during the three months ended March 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:

	Three Months Ended March 31, 2019
Operating cash flow information:	
Cash paid for amounts included in the measurement of lease liabilities	$ 3,977
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	March 31, 2019
Right-of-use assets	Other assets	$ 39,353
Current lease liabilities	Accrued expenses and other current liabilities	$ 26,234
Non-current lease liabilities	Other liabilities	$ 13,119

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 our condensed consolidated financial statements. The leases would have resulted in a combined increase in total assets of approximately $11,000 and a combined increase in total liabilities of approximately $12,000 in our March 31, 2019 condensed consolidated balance sheet, respectively, and would not have a material impact on our 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 expires in November 2019. As of March 31, 2019, total minimum lease payments on these leases are $12,449.

12. Related Party Transactions

The Company has entered into various research, development, license and supply agreements with Serum Institute and the Company's controlling stockholder, Pharmsynthez (as well as SynBio, a wholly owned subsidiary of Pharmsynthez), each a related party whose relationship and ownership has not materially changed from that disclosed in the Company's Annual Report on Form 10-K for the years ended December 31, 2018 filed with the SEC on March 29, 2019 as amended on April 30, 2019.

The Company has agreed to acquire the XCART technology platform from Hesperix and OPKO. Dr. Genkin is a director and significant shareholder of Hesperix. In addition, the Company has agreed to repay a $150,000 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.

13. Subsequent Events

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

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, 2018 and 2017, and the related consolidated statements of comprehensive loss, stockholder's equity and cash flows for each of the two years in the period ended December 31, 2018 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, 2018 and 2017, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

Explanatory Paragraph/Going Concern

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

Basis for Opinion

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

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

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

/s/ Marcum llp

Marcum llp

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

Boston, Massachusetts
March 29, 2019

XENETIC BIOSCIENCES, INC.
CONSOLIDATED BALANCE SHEETS

	December 31, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash	$ 571,605	$ 5,533,062
Restricted cash	66,510	66,510
Prepaid expenses and other	555,856	285,005
Total current assets	1,193,971	5,884,577
Property and equipment, net	4,956	27,846
Goodwill	3,283,379	3,283,379
Indefinite-lived intangible assets	9,243,128	9,243,128
Other assets	705,660	724,713
Total assets	$ 14,431,094	$ 19,163,643
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 934,147	$ 786,779
Accrued expenses	664,029	1,135,653
Other current liabilities	1,612	21,234
Total current liabilities	1,599,788	1,943,666
Deferred tax liability	2,918,518	2,918,518
Total liabilities	$ 4,518,306	$ 4,862,184
Commitments and contingent liabilities (Note 12)		
Stockholders' equity:		
Preferred stock, 10,000,000 shares authorized		
Series B, $0.001 par value: 1,804,394 and 2,120,742 shares issued and outstanding as of December 31, 2018 and December 31, 2017, respectively	1,804	2,120
Series A, $0.001 par value: 970,000 shares issued and outstanding as of December 31, 2018 and December 31, 2017	970	970
Common stock, $0.001 par value; 45,454,546 shares authorized as of December 31, 2018 and December 31, 2017; 9,727,774 and 9,041,426 shares issued as of December 31, 2018 and December 31, 2017, respectively; 9,403,889 and 8,717,541 shares outstanding as of December 31, 2018 and December 31, 2017, respectively	9,726	9,040
Additional paid in capital	168,161,329	165,249,912
Accumulated deficit	(153,233,595)	(145,933,137)
Accumulated other comprehensive income	253,734	253,734
Treasury stock	(5,281,180)	(5,281,180)
Total stockholders' equity	9,912,788	14,301,459
Total liabilities and stockholders' equity	$ 14,431,094	$ 19,163,643

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,	
	2018	**2017**
Revenue		
Licenses	$ –	$ 7,500,000
Collaboration services	–	85,000
Total revenue	–	7,585,000
Operating costs and expenses:		
Cost of research and development revenue	–	(156,119)
Research and development	(2,883,952)	(4,060,000)
General and administrative	(4,392,375)	(6,937,643)
Loss from operations	(7,276,327)	(3,568,762)
Other income (expense):		
Other expense	(24,640)	(24,552)
Interest income (expense)	509	(1,818)
Total other expense	(24,131)	(26,370)
Net loss	$ (7,300,458)	$ (3,595,132)
Basic and diluted loss per share	$ (0.80)	$ (0.41)
Weighted-average shares of common stock outstanding, basic and diluted	9,070,883	8,665,763

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

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

	Preferred Stock		Common Stock						
	Number of Shares	Par Value ($0.001)	Number of Shares	Par Value ($0.001)	Additional Paid in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Treasury Stock	Total Stockholders' Equity
Balance as of January 1, 2017	3,275,742	$ 3,275	8,731,029	$ 8,730	$ 163,522,921	$ (142,338,005)	$ 253,734	$ (5,281,180)	$ 16,169,475
Conversion of notes	–	–	125,397	125	(125)	–	–	–	–
Conversion of Series B preferred stock to shares of common stock	(185,000)	(185)	185,000	185	–	–	–	–	–
Share-based expense	–	–	–	–	1,784,129	–	–	–	1,784,129
Common stock awards to vendors	–	–	–	–	69,303	–	–	–	69,303
Warrant expense	–	–	–	–	(126,316)	–	–	–	(126,316)
Net loss	–	–	–	–	–	(3,595,132)	–	–	(3,595,132)
Balance as of December 31, 2017	3,090,742	$ 3,090	9,041,426	$ 9,040	$ 165,249,912	$ (145,933,137)	$ 253,734	$ (5,281,180)	$ 14,301,459
Exercise of warrants	–	–	370,000	370	1,479,630	–	–	–	1,480,000
Conversion of Series B preferred stock to shares of common stock	(316,348)	(316)	316,348	316	–	–	–	–	–
Share-based expense	–	–	–	–	1,351,873	–	–	–	1,351,873
Common stock awards to vendors	–	–	–	–	69,708	–	–	–	69,708
Warrant expense	–	–	–	–	10,206	–	–	–	10,206
Net loss	–	–	–	–	–	(7,300,458)	–	–	(7,300,458)
Balance as of December 31, 2018	2,774,394	$ 2,774	9,727,774	$ 9,726	$ 168,161,329	$ (153,233,595)	$ 253,734	$ (5,281,180)	$ 9,912,788

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,	
	2018	**2017**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (7,300,458)	$ (3,595,132)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Depreciation	15,827	23,784
Gain on sale of property and equipment	(15,437)	–
Share-based expense	1,351,873	1,784,129
Warrant-based expense for services	10,206	(126,316)
Vendor share-based payments	69,708	135,280
Changes in operating assets and liabilities:		
Accounts receivable	–	3,000,000
Prepaid expenses and other assets	(251,798)	280,633
Accounts payable, accrued expenses and other liabilities	(343,878)	(8,183)
Net cash (used in) provided by operating activities	(6,463,957)	1,494,195
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	–	(9,264)
Proceeds from sale of property and equipment	22,500	–
Net cash provided by (used in) investing activities	22,500	(9,264)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of warrants	1,480,000	–
Net cash provided by financing activities	1,480,000	–
Net change in cash and restricted cash	(4,961,457)	1,484,931
Cash and restricted cash at beginning of period	5,599,572	4,114,641
Cash and restricted cash at end of period	$ 638,115	$ 5,599,572
SUPPLEMENTAL CASH FLOW INFORMATION:		
Cash paid for interest	$ 599	$ 1,932
SUPPLEMENTAL SCHEDULE OF NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Conversion of Series B preferred stock to common stock	$ 316	$ 185
Reclassification of common shares issuable to accounts payable	$ –	$ 65,977
Issuance of common stock for promissory note converted in 2016	$ –	$ 125

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

1. The Company

Background

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

Xenetic incorporates its patented and proprietary technologies into a number of drug candidates 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. While the Company primarily focuses on researching and developing oncology drugs, it also has significant interests in drugs being developed by its collaborators to treat other conditions.

Xenetic's most advanced investigational drug candidate is oncology therapeutic XBIO-101 (sodium cridanimod) for the treatment of progestin resistant endometrial cancer. The Company has exclusive rights to develop and commercialize XBIO-101 worldwide, except for specified countries in the Commonwealth of Independent States ("CIS"). XBIO-101 has been granted orphan drug designation by the United States ("U.S.") Food and Drug Administration ("FDA") for the potential treatment of progesterone receptor negative ("PrR-") endometrial cancer in conjunction with progesterone therapy. The Company's Phase II trial for XBIO-101 commenced patient dosing in October 2017. The Company 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.

Xenetic's lead proprietary technology is PolyXen™, 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. 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"). The Company believes this technology may be applied to a variety of drug candidates to enhance the properties of the therapeutic, potentially providing advantages over competing products.

On March 1, 2019, the Company entered into an agreement to acquire the novel CAR T ("Chimeric Antigen Receptor T Cell") platform technology, referred to herein as "XCART," (the "Transaction") a proximity-based screening platform capable of identifying CAR constructs that can target patient-specific tumor neoantigens, with a demonstrated proof of mechanism in B-cell Non-Hodgkin 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.

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, 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. Xenetic's clinical development program will seek to confirm the early preclinical results, and to demonstrate a more attractive safety profile than existing therapies.

The closing of the Transaction is subject to customary closing conditions as well as conditions regarding (i) the Company having adequate financing to fund its future working capital obligations following the closing and (ii) the Company obtaining necessary and appropriate stockholder approvals, evidencing among other matters, approval of the Share Purchase Agreement and the transactions contemplated thereunder, including the issuance of shares of the Company's common stock. Subject to the satisfaction of the closing conditions, the Transaction is expected to close in the first half of 2019. See Note 14 "*Subsequent Events*".

Xenetic's drug candidates have resulted from its research activities or those of its collaborators and are in the development stage. As a result, the Company continues to commit a significant amount of its resources to its research and development activities and anticipates continuing to do so for the near future. To date, none of the Company's drug candidates have received regulatory marketing authorization in the U.S. by the FDA nor in any other territories by any applicable agencies. Although the Company holds a broad patent portfolio, the focus of its internal development efforts was limited in 2018 to research and development of its primary product candidate XBIO-101 due to capital constraints. The Company intends to pursue development efforts of the XCART technology once the acquisition is consummated and pursue other developments efforts around CAR T technology. The Company also plans to research potential utilities for XBIO-101 alone or in combination, in immuno-oncology approaches and will continue to look for potential partner and out-licensing opportunities for its platform technologies subject to adequate funding.

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

The Company incurred a net loss of approximately $7.3 million for the year ended December 31, 2018. The Company had an accumulated deficit of approximately $153.2 million as of December 31, 2018 as compared to an accumulated deficit of approximately $145.9 million as of December 31, 2017. Working capital (deficit) was approximately $(0.4) million at December 31, 2018 and approximately $3.9 million at December 31, 2017. The Company expects to continue incurring losses for the foreseeable future and will need to raise additional capital or pursue other strategic alternatives in the very near term in order to continue pursuit of its business plan and continue as a going concern.

The Company believes that it has access to capital resources through possible public or private equity offerings, debt financings, corporate collaborations, related party funding or other means. On March 5, 2019, the Company raised $3.1 million in a registered direct common stock offering resulting in $2.7 million of net proceeds to the Company. However, it has not secured any commitment for additional financing at this time. The terms, timing and extent of any future financing will depend upon several factors, including the achievement of progress in its clinical development programs, its ability to identify and enter into licensing or other strategic arrangements, and factors related to financial, economic and market conditions, many of which are beyond its control.

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

2. Summary of Significant Accounting Policies

Preparation of Financial Statements

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

Principles of Consolidation

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

Use of Estimates

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

Functional Currency Change

Effective April 1, 2015, the functional currency of the Company's foreign subsidiaries changed from the British Pound Sterling to the 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 7, *Fair Value Measurements*, for discussion of the Company's fair value measurements.

Cash and Cash Equivalents

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

Restricted Cash

As of December 31, 2018 and 2017, restricted cash represents a certificate of deposit that matures annually and secures the Company's outstanding letter of credit of approximately $0.1 million for its former operating lease in Lexington, Massachusetts (the "Lexington Lease"). The Lexington Lease expired in January 2019 and the letter of credit is required to be maintained through May 1, 2019.

In November 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash* that changes the presentation of restricted cash and cash equivalents on the statement of cash flows. Restricted cash and restricted cash equivalents are included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. ASU 2016-18 was effective for the Company in the first quarter of fiscal 2018. Adoption of this standard resulted in reclassification of restricted cash in the consolidated statements of cash flows for the year ended December 31, 2017.

Concentration of Credit Risk

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

Property and Equipment

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

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

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

Indefinite-Lived Intangible Assets

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

The Company assesses intangible assets with indefinite lives for impairment at least annually as of October 1, or when events or changes in the business environment indicate the carrying value may be impaired. The Company also has the option to first assess qualitative factors to determine whether the existence of events 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.

No impairment was recorded during the years ended December 31, 2018 and 2017.

Goodwill

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

No impairment was recorded during the years ended December 31, 2018 and 2017.

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, 2018 and 2017.

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 and continue to be reported in accordance with ASC 605. 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 605, the Company recognized revenue when all of the following criteria were met: (i) persuasive evidence of an arrangement existed; (ii) delivery had occurred or services had been rendered; (iii) the seller's price to the buyer was fixed or determinable; and (iv) collectability was reasonably assured.

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 fulfil the Company's performance obligations, which may include technology transfer assistance, research activities, clinical development activities, and manufacturing activities from development through the commercialization of the product. Given the uncertainties of these collaboration arrangements, significant judgment is required to determine the duration of the performance period.

When 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.

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).

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 it in arrears for services performed, on a pre-determined schedule or when contractual milestones are met. However, some require advanced payments. The Company makes estimates of accrued expenses as of each balance sheet date in the financial statements based on facts and circumstances known at that time. The Company periodically confirms the accuracy of the estimates with the service providers and 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, 2018, the Company has recorded accrued program expense of approximately $0.2 million as a component of accrued expenses. In addition, the Company has recorded approximately $0.4 million of deposits held with our clinical trial vendors as a component of prepaid expenses and other current assets as of December 31, 2018. At December 31, 2017, the Company had recorded $33,000 as a component of deferred program expenses as a component of prepaid expenses and other current assets.

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 actual volatility of the Company and of comparable public companies over the expected term of the option. The expected terms represent the time that options are expected to be outstanding. The Company accounts for forfeitures as they occur and not at the time of grant. The Company has not paid dividends and does not anticipate paying cash dividends in the foreseeable future and, accordingly, uses an expected dividend yield of zero. The risk-free interest rate is based on the rate of U.S. Treasury securities with maturities consistent with the estimated expected term of the awards. Upon exercise, stock options are redeemed for newly issued shares of common stock. RSUs are redeemed for newly issued shares of common stock as the vesting 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.

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

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

Common stock awards

The Company grants common stock awards to non-employees in exchange for services provided. The Company measures the fair value of these awards using the fair value of the services provided, 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 9, *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, 2018 and 2017, there were approximately 0.3 million JSOP awards issued.

For the years ended December 31, 2018 and 2017, 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, 2018 and 2017, approximately 0.8 million and 0.6 million potentially dilutive securities, respectively, were deemed anti-dilutive.

Segment Information

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

Operating Leases

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

Acquisitions

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

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

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

Recent Accounting Standards

In June 2018, the FASB issued ASU 2018-07*, Compensation – Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting.* ASU 2018-07 expands 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 nonemployees 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 is effective for the Company in the first quarter of fiscal 2019. The adoption of ASU 2018-07 is not expected to have a significant impact on the Company's consolidated financial statements.

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

In February 2016, FASB issued ASU 2016-02, *Leases (Topic 842)* ("ASU 2016-02"). ASU 2016-02 will require lessees to recognize a lease liability and a right-of-use asset for all leases, with the exception of short-term leases, at the commencement date. This guidance is effective for annual reporting periods beginning after December 15, 2018, including interim periods within those annual periods. Early application is permitted. The adoption of ASU 2016-02 is not expected to have a significant impact on the Company's consolidated financial statements.

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

3. 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 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. The first program under this agreement was a next generation rFVIII protein product candidate ("SHP656").

In December 2016, Takeda reached a milestone of its Phase I/II clinical trial for the treatment of hemophilia with SHP656, triggering a $3.0 million payment to be paid to the Company pursuant to the agreement with Takeda. The Company determined the milestone to be non-substantive because all significant performance obligations to achieve the contingent payments were the responsibility of Takeda with only negligible amount by the Company of effort to fulfill its obligations, specifically assistance on a research committee. As the amount allocable to the remaining performance period was negligible, the Company recognized the full $3.0 million in milestone revenue in connection with this collaboration during the year ended December 31, 2016. The payment was made in January 2017.

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

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. The Company recognized the full $7.5 million as license revenue in connection with this Sublicense Agreement during the year ended December 31, 2017. There have been no royalty payments under the Sublicense Agreement to date.

SynBio LLC

In August 2011, SynBio LLC ("SynBio") and the Company entered into a stock subscription and collaborative development of pharmaceutical products agreement (the "Co-Development Agreement"). The Company granted an exclusive license to SynBio to develop pharmaceutical products using certain molecule(s) based on SynBio's technology and the Company's proprietary technology (PolyXen, OncoHist and ImuXen) that prolongs the active life and/or improves the pharmacokinetics of certain therapeutic proteins and peptides (as well as conventional drugs). In return, SynBio granted an exclusive license to the Company to use the 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, 2018, 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, 2018 and 2017.

In 2017, SynBio became a wholly-owned subsidiary of Pharmsynthez and all ownership percentages previously held by SynBio are combined with Pharmsynthez. See Note 9, *Stockholders' Equity.*

Serum Institute of India Limited

In August 2011, the Company entered into a collaborative research and development agreement with Serum Institute providing Serum Institute an exclusive license to use the Company's PolyXen technology to research and develop one potential commercial product, Polysialylated Erythropoietin ("PSA-EPO"). Serum Institute is responsible for conducting all 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, 2018, 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, 2018 and 2017.

Serum Institute is a related party of the Company with a share ownership of approximately 6.7% and 7.2% of the total issued common stock of the Company as of December 31, 2018 and 2017, respectively. In addition to its' common stock ownership, Serum Institute holds outstanding warrants to purchase the Company's common stock. See Note 9, *Stockholders' Equity.*

PJSC Pharmsynthez

In November 2009, the Company entered into a collaborative research and development license agreement with Pharmsynthez (the "Pharmsynthez Arrangement") pursuant to which the Company granted an exclusive license to Pharmsynthez to develop, commercialize and market six drug candidates based on the Company's PolyXen and ImuXen technology in certain territories. In exchange, Pharmsynthez granted an exclusive license to the Company to use any 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 controlling stockholder of the Company with a share ownership of approximately 57.1% and 61.5% of the total issued common stock of the Company as of December 31, 2018 and 2017, respectively. In addition to its common stock ownership, Pharmsynthez holds outstanding warrants to purchase the Company's common stock, approximately 1.5 million shares of the Company's issued and outstanding Series B Preferred Stock, and all of the Company's issued and outstanding Series A Preferred Stock through its wholly-owned subsidiary, SynBio. See Note 9, *Stockholders' Equity*.

4. Property and Equipment, net

Property and equipment, net consists of the following:

	December 31, 2018	December 31, 2017
Laboratory equipment	$ –	$ 264,583
Office and computer equipment	42,289	46,634
Leasehold improvements	26,841	26,841
Furniture and fixtures	20,263	20,263
Property and equipment – at cost	89,393	358,321
Less accumulated depreciation	(84,437)	(330,475)
Property and equipment – net	$ 4,956	$ 27,846

Depreciation expense was approximately $16,000 and $24,000 for the years ended December 31, 2018 and 2017, respectively. During the year ended December 31, 2018, the Company sold certain laboratory equipment for $22,500 resulting in an approximate $15,000 gain.

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

Goodwill

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

Balance as of January 1, 2017	$ 3,283,379
No changes	–
Balance as of December 31, 2017	$ 3,283,379
No changes	–
Balance as of December 31, 2018	$ 3,283,379

As of October 1, 2018 and 2017, the dates of the Company's annual impairment review, the fair value of the Company's goodwill balance exceeded its carrying value.

Indefinite-Lived Intangible Assets

The Company's indefinite-lived intangible asset, OncoHist, is IPR&D relating to the Company's business combination with SymbioTec in 2012. The carrying value of OncoHist was approximately $9.2 million as of December 31, 2018 and 2017. No impairment was recorded during the years ended December 31, 2018 and 2017. OncoHist is not yet commercialized and, therefore, has not yet begun to be amortized as of December 31, 2018.

Other Long-Term Assets

On September 15, 2016, the Company issued approximately 0.2 million shares of common stock to Serum Institute in exchange for approximately $0.8 million of research and development and clinical PSA supply as well as settlement of approximately $0.2 million of prior purchases of PSA supply. Approximately $0.1 million of the clinical supply was utilized and expensed during the year ended December 31, 2017. No clinical supply was utilized during the year ended December 31, 2018. The Company has classified the remaining $0.7 million as long-term as it does not anticipate utilizing the majority of the PSA supply within the next 12 months.

6. Accrued Expenses

Accrued expenses consist of the following:

	December 31, 2018	December 31, 2017
Accrued payroll and benefits	$ 53,541	$ 723,488
Accrued professional fees	394,075	389,086
Accrued research costs	205,067	11,477
Other	11,346	11,602
	$ 664,029	$ 1,135,653

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

7. 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, 2018 and 2017.

8. 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,	
	2018	2017
Domestic (U.S.)	$ (3,824,673)	$ (5,889,926)
Foreign (U.K.)	(3,379,268)	2,398,830
Foreign (Germany)	(96,517)	(104,036)
Loss before income taxes	$ (7,300,458)	$ (3,595,132)

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,	
	2018	2017
Federal	$ (1,533,096)	$ (1,222,345)
State	(238,952)	(303,315)
Increase in tax losses not recognized	1,695,482	(359,833)
Permanent differences, net	40,015	162,543
Foreign rate differential	124,294	(383,601)
Share-based payments, net	20,441	(22,087)
Changes per enacted tax reform	–	2,320,059
Enhanced research and development tax credits	(108,184)	(191,421)
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,	
	2018	2017
Deferred tax assets:		
U.K. net operating loss carryforwards	$ 8,039,343	$ 7,641,719
U.K. capital loss carryforwards	1,298,303	1,378,643
U.S. federal net operating loss carryforwards	3,184,691	2,606,017
IPR&D	6,108,078	6,776,473
Share-based payments	1,859,357	1,527,615
Enhanced research and development tax credits	1,109,026	1,060,200
Germany net operating loss carryforwards	524,093	516,401
U.S. state net operating loss carryforwards	1,298,745	1,057,856
Accrued expenses	59,979	198,067
Depreciation	3,283	1,948
Other	–	–
Total deferred tax assets before valuation allowance	23,484,898	22,764,939
Valuation allowance for deferred tax assets	(23,484,898)	(22,764,939)
Deferred tax liabilities:		
Indefinite-lived intangible asset	(2,918,518)	(2,918,518)
Debt discount	–	–
Total deferred tax liabilities	(2,918,518)	(2,918,518)
Net deferred liability	$ (2,918,518)	$ (2,918,518)

For the years ended December 31, 2018 and 2017, the Company had U.K. net operating loss carryforwards of approximately $47.3 million and $45.0 million, respectively, U.S. federal net operating loss carryforwards of approximately $16.5 million and $13.5 million, respectively, U.S. state net operating loss carryforwards of approximately $16.2 million and $13.3 million, respectively, and Germany net operating loss carryforwards of approximately $1.7 million and $1.6 million, respectively. The U.K. and Germany net operating loss carryforwards can be carried forward indefinitely. $3.0 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.

On December 22, 2017, the U.S. enacted new tax reform ("Tax Cuts and Jobs Act"). The Tax Cuts and Jobs Act contains provisions with separate effective dates but is generally effective for taxable years beginning after December 31, 2017. Beginning with the year ending December 31, 2018, the corporate statutory rates on U.S. earnings were reduced from 34% to 21%. The impact of the rate reduction for the year ending December 31, 2017, was approximately $2.3 million relating to the revaluation of the net deferred tax assets. Other than the reduction in statutory rate, the Company does not anticipate the regulations will have a material impact on income taxes in future years. The Tax Cuts and Jobs Act also contains a provision requiring companies to repatriate all aggregate post 1986 earnings and profits of foreign corporations. The Company estimated that the repatriation will be zero under a provisional basis under SAB118. The final calculations under tax reform resulted in no change to the amounts estimated.

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

As of December 31, 2018 and 2017, 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 2013 through 2018 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, 2018. 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, 2018, the Company had no material unrecognized tax benefits and no adjustments to liabilities or operations were required. No interest and penalties have been recognized by the Company to date.

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

9. Stockholders' Equity

Common Stock

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

In March 2017, the Company issued approximately 0.1 million shares of the Company's common stock to Pharmsynthez in connection with the conversion by Pharmsynthez of its $500,000, 10% convertible promissory note as a result of the Company's underwritten public offering in November 2016 and Pharmsynthez subsequently exercising its rights to the shares. The shares issued to Pharmsynthez represent both owed principal and accrued interest.

The holders of Series B Preferred Stock converted approximately 0.3 million shares and 0.2 million shares into the same number of shares of common stock during the years ended December 31, 2018 and December 31, 2017, respectively.

During the year ended December 31, 2018, 0.4 million warrants were exercised resulting in the issuance of 0.4 million shares of common stock. There were no exercises of warrants during the year ended December 31, 2017.

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

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

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

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

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

Redemption. Upon 30 days prior written notice, the Company may require the holder of any Series A Preferred Stock to convert any or all of such holder's Series A Preferred Stock to common stock at a rate of one share of Series A Preferred Stock to one share of common stock.

As of December 31, 2018 and 2017, there were approximately 1.0 million shares of Series A Preferred Stock issued and outstanding which are convertible into the same number of shares of common stock.

Series B Preferred Stock

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

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

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

Subsequent Equity Sales. The Series B Preferred Stock has full ratchet price based anti-dilution protection, subject to 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. Subsequent to year end, the Company entered into a down-round financing event resulting in an adjustment to the conversion ratio. See Note 14 Subsequent Events for further details.

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

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

As of December 31, 2018 and 2017, there were approximately 1.8 million and approximately 2.1 million shares of Series B Preferred Stock issued and outstanding which are convertible into the same number of shares of common stock. The holders of Series B Preferred Stock converted approximately 0.3 million shares and 0.2 million shares into the same number of shares of common stock during the years ended December 31, 2018 and December 31, 2017, respectively.

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, 2018 and December 31, 2017, warrants to purchase 539,202 and 646,249 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. For the years ended December 31, 2018 and 2017, the Company recognized expense of approximately $10,000 and a gain of approximately $0.1 million, respectively, related to collaboration and consulting warrants.

On December 31, 2014, SynBio was granted a warrant to purchase 204,394 new shares of common stock at an exercise price of $25.41 per share ("SynBio 2014 Warrant"). The SynBio 2014 Warrant is exercisable in four equal tranches, each with separate non-market, performance-based vesting criteria. The Company uses its judgment to assess the probability and timing of SynBio achieving these vesting criteria and estimated that it is not probable that the vesting criteria for any tranche will be achieved. 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, 2018 and 2017.

In connection with the SynBio 2014 Warrant grant, warrants to purchase 9,697 aggregate new shares of common stock were issued to SynBio and Pharmsynthez non-director designees ("SynBio Partner Warrants") on December 31, 2014 under the same terms and conditions of the SynBio 2014 Warrant. The vesting criteria for any tranche were not met and, as a result, the Company did not recognize expense related to the SynBio Partner Warrants during the years ended December 31, 2018 and 2017.

On December 31, 2014, the Company granted Serum Institute a warrant to purchase 96,970 new shares of common stock at an exercise price of $7.92 per share, as adjusted ("Serum Institute 2014 Warrant"). The Serum Institute 2014 Warrant is exercisable in two equal tranches, each with separate non-market, performance-based vesting criteria. The Company uses its judgment to assess the probability and timing of Serum Institute achieving these vesting criteria and estimated that it is probable that the vesting criteria will be achieved for each tranche. These judgments are reassessed at each reporting period until the measurement date is reached.

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

In 2016, the Company issued 212,122 warrants to purchase shares of common stock to Serum Institute with an exercise price of $7.92. The new warrants were fully vested and expensed at the time of grant.

The Company recognized warrant expense (income) of approximately $10,000 and $(0.1) million during the years ended December 31, 2018 and 2017, respectively, related to the Serum Institute 2014 Warrant and Serum Institute Partner Warrants. No collaboration or consulting service warrants were exercised or granted during the years ended December 31, 2018 and 2017. These warrants have an average weighted exercise price of $10.41 and expiration dates ranging from December 2019 through May 2021.

Warrants Related to Financing Arrangements

As of December 31, 2018 and 2017 there were outstanding warrants related to financing agreements to purchase an aggregate of 3,152,225 shares and 3,522,225 shares of Common Stock at an average weighted exercise price of $4.33 and $4.30, respectively. During the year ended December 31, 2018, warrants to purchase 370,000 shares of common stock were exercised resulting in approximately $1.5 million of net proceeds to the Company. There were no warrants exercised during the year ended December 31, 2017. No warrants related to financing agreements were granted during the years ended December 31, 2018 and 2017. These warrants have expiration dates ranging from July 1, 2020 through November 2021.

10. Share-Based Expense

Total share-based expense related to stock options, RSUs, common stock awards, and non-financing warrants was approximately $1.4 million and $1.8 million for the years ended December 31, 2018 and 2017, respectively. (See Note 9, *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,	
	2018	**2017**
Research and development expenses	$ 203,030	$ 101,401
General and administrative expenses	1,228,757	1,691,692
	$ 1,431,787	$ 1,793,093

Stock Option Modifications

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

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

Stock Options

The Company grants stock option awards and RSUs to employees and non-employees with varying vesting terms under the Xenetic Biosciences, Inc. Amended and Restated Equity Incentive Plan ("Stock Plan"). The Company measures the fair value of stock option awards using the Black-Scholes option pricing model, which uses the assumptions noted in the tables below, including the risk-free interest rate, expected term, share price volatility, dividend yield and forfeiture rate. The risk-free interest rate is based upon the U.S. Treasury yield curve in effect at the time of grant, with a term that approximates the expected life of the option. For employee stock options issued in 2018 and 2017 that qualify as "plain vanilla" stock options, the expected term is based on the simplified method. The Company has a limited history of stock option exercises, which does not provide a reasonable basis for the Company to estimate the expected term of employee stock options. For all other employee stock options, the Company estimates the expected life using judgment based on the anticipated research and development milestones of the Company's clinical projects and behavior of the Company's employees. The expected life of non-employee options is the contractual life of the option. The Company determines the expected volatility based on a blended volatility rate of its own historical volatility with that of comparable publicly traded companies with drug candidates in similar therapeutic areas and stages of nonclinical and clinical development to the Company's drug candidates. The Company has applied an expected dividend yield of 0% as the Company has not historically declared a dividend and does not anticipate declaring a dividend during the expected life of the options. Effective January 1, 2017, the Company adopted ASU 2016-09 and elected to account for forfeitures as they occur.

Employee Stock Options

During the years ended December 31, 2018 and 2017, 100,000 and 700,000 total stock options to purchase shares of common stock were granted by the Company, respectively. The weighted average grant date fair value per option share was $2.63 and $2.70, respectively. No stock options were exercised during the years ended December 31, 2018 and 2017.

During the years ended December 31, 2018 and 2017, 524,540 and 340,930 total stock options vested, with total fair values of approximately $1.6 million and $1.9 million, respectively. As of December 31, 2018, there was approximately $1.0 million of unrecognized share-based payments related to employee stock options that are expected to vest. The Company expects to recognize this expense over a weighted-average period of approximately 1.3 years.

Key assumptions used in the Black-Scholes option pricing model for options granted to employees during the years ending December 31, 2018 and 2017 are as follows:

	Year Ended December 31,	
	2018	**2017**
Weighted-average expected dividend yield (%)	–	–
Weighted-average expected volatility (%)	118.03	111.37
Weighted-average risk-free interest rate (%)	2.90	1.79
Weighted-average expected life of option (years)	5.90	5.36
Weighted-average exercise price ($)	3.05	3.34

The following is a summary of employee stock option activity for the years ended December 31, 2018 and 2017:

	Number of shares	**Weighted-average exercise price**	**Weighted-average remaining life (years)**	**Aggregate intrinsic value**
Outstanding as of January 1, 2017	1,193,712	$ 4.43	8.94	$ 526,073
Granted	700,000	3.34		
Expired	(113,343)	4.61		
Outstanding as of December 31, 2017	1,780,369	3.99	8.53	$ 5,273
Granted	100,000	3.05		
Expired	(110,929)	5.73		
Outstanding as of December 31, 2018	1,769,440	$ 3.83	8.17	$ –
Vested or expected to vest as of December 31, 2018	1,744,440	$ 3.85	8.16	$ –
Exercisable as of December 31, 2017	731,895	$ 4.84	7.44	$ 5,273
Exercisable as of December 31, 2018	1,152,173	$ 4.11	7.92	$ –

A summary of the status of the Company's non-vested employee stock option shares as of December 31, 2018, and the changes during the year ended December 31, 2018, is as follows:

	Number of shares	**Weighted-average grant date fair value**
Balance as of January 1, 2018	1,048,474	$ 2.86
Granted	100,000	$ 2.63
Forfeited	(6,667)	$ 2.91
Vested	(524,540)	$ 3.05
Balance as of December 31, 2018	617,267	$ 2.65

Restricted Stock Units

For the year ended December 31, 2017, the Company granted 50,000 RSUs. There were no RSU grants for the year ended December 31, 2018. The RSUs vest annually over a 3-year period and had a grant date fair value of $2.11. During the year ended December 31, 2018, 16,667 RSUs were vested and none expired.

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. Compensation expense related to stock options granted to non-employees is subject to re-measurement at each reporting period until the options vest.

During the year ended December 31, 2018, 10,000 total stock options to purchase shares of common stock were granted by the Company to non-employees. No options were granted to non-employees and none were exercised during the year ended December 31, 2017.

During the year ended December 31, 2018 and 2017, 10,000 and 10,101 total stock options vested, with total fair values of approximately $36,000 and $0.1 million, respectively. As of December 31, 2018, all non-employees stock options had vested. For the years ended December 31, 2018 and 2017, the Company recognized approximately $36,000 and $0.1 million, 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, 2018 and 2017:

	Number of shares	Weighted-average exercise price	Weighted-average remaining life (years)	Aggregate intrinsic value
Outstanding as of January 1, 2017	57,442	$ 7.57	7.23	$ –
Expired	(723)	10.34		
Outstanding as of December 31, 2017	56,719	7.53	6.31	$ –
Granted	10,000	1.93		
Expired	(3,148)	18.25		
Outstanding as of December 31, 2018	63,571	$ 6.12	5.40	$ –
Vested or expected to vest as of December 31, 2018	63,571	$ 6.12	5.40	$ –
Exercisable as of December 31, 2017	56,719	$ 7.53	6.31	$ –
Exercisable as of December 31, 2018	63,571	$ 6.12	5.40	$ –

A summary of the status of the Company's non-vested non-employee stock option shares as of December 31, 2018, and the changes during the year ended December 31, 2018 is as follows:

	Number of shares	Weighted-average grant date fair value
Balance as of January 1, 2018	–	$ –
Granted	10,000	$ 1.73
Vested	(10,000)	$ 1.73
Balance as of December 31, 2018	–	$ –

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, 2018 and 2017 are as follows:

	Number of shares
Balance as of January 1, 2017	29,790
Granted	41,800
Issued	(8,773)
Balance as of December 31, 2017	62,817
Granted	26,000
Issued	–
Balance as of December 31, 2018	88,817

The Company granted 26,000 and 41,800 shares of common stock during the years ended December 31, 2018 and 2017, respectively, in exchange for professional services. As all services were rendered in each respective period, expense related to common stock awards of approximately $0.1 million and $0.1 million was recognized during the years ended December 31, 2018 and 2017, respectively. The balance of the common stock awards has not been issued as of December 31, 2018.

Joint Share Ownership Plan

As of December 31, 2018 and 2017, there were approximately 0.3 million JSOP awards issued and outstanding to two former senior executives, respectively. Under the JSOP, shares in the Company are jointly purchased at fair market value by the participating executives and the trustees of the JSOP trust, with such shares held in the JSOP trust. For U.S. GAAP purposes the awards were valued as employee options and recorded as a reduction in equity as treasury shares until they are exercised by the employee. The JSOP awards are fully vested and have no expiration date. There were no compensation charges during the years ended December 31, 2018 and 2017, respectively.

11. 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 year ended December 31, 2018. The Company made contributions of approximately $51,000 to the 401(k) Plan for the year ended December 31, 2017.

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, 2018 and December 31, 2017, respectively.

12. Commitments and Contingent Liabilities

Leases

In August 2013, the Company entered into the Lexington Lease to lease office and laboratory space under an operating lease with a commencement date of January 1, 2014 and a termination date of January 31, 2019. With the execution of this lease, the Company is required to maintain a $66,000 letter of credit as a security deposit. The letter of credit is secured by a certificate of deposit, which is classified as restricted cash within the consolidated balance sheets. The letter of credit is required to be maintained through May 1, 2019.

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

The Company's contractual commitments under all non-cancelable operating leases as of December 31, 2018, are as follows:

As of December 31,	Total Operating Leases
2019	$ 24,583
2020	–
Total minimum lease payments	$ 24,583

Rent expense is calculated on a straight-line basis over the term of the leases. Rent expense under the Company's operating leases was approximately $0.1 million for the years ended December 31, 2018 and 2017, respectively.

Subsequent to year end, the Lexington Lease expired and the Company relocated its corporate headquarters to Framingham, Massachusetts. The new lease commenced in January 2019 and has a termination date of September 30, 2020. The total contractual commitment of approximately $50,000 associated with the new lease is not reflected in the table above.

Litigation

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

13. Related Party Transactions

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

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

Please refer to Note 3, *Significant Strategic Drug Development Collaborations – Related Parties* and Note 9, *Stockholder's Equity*, for details on arrangements with collaboration partners that are also related parties.

14. Subsequent Events

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

XCART Transaction

On March 1, 2019 (the "Signing Date"), the Company entered into 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 (the "Sellers' Representative"), pursuant to which the Company will purchase from Sellers all of the issued and outstanding shares of capital stock (the "Shares") of Hesperix.

Under the terms of the Share Purchase Agreement, the Company will issue to Sellers an aggregate of Four Million Eight Hundred Seventy-Five Thousand (4,875,000) shares of the Company's common stock (the "Transaction Shares"), regardless of the trading price per share of the Company's common stock 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 expects to issue the Transaction Shares pursuant to a registration statement on Form S-4.

The closing of the Transaction is subject to customary closing conditions as well as conditions regarding (i) the Company having adequate financing to fund its future working capital obligations following the closing and (ii) the Company obtaining necessary and appropriate stockholder approvals, evidencing among other matters, approval of the Share Purchase Agreement and the transactions contemplated thereunder, including the issuance of the Transaction Shares. Subject to the satisfaction of the closing conditions, the Transaction is expected to close in the first half of 2019. The Company is currently evaluating the accounting impacts associated with the Transaction.

On the Signing Date and in connection with the Transaction, Hesperix entered into an assignment agreement (the "Hesperix Assignment Agreement") with the 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 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 (the "OPKO Assignment Agreement") with OPKO Pharmaceuticals, LLC ("OPKO"), 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 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 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 will issue One Million Nine Hundred Sixty-Eight Thousand Seven Hundred Fifty (1,968,750) shares of the Company's common stock to OPKO and Six Hundred Fifty-Six Thousand Two Hundred Fifty (656,250) shares of the Company's common stock to the Institute regardless of the trading price per share of the Company's common stock 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.

Financing

On March 5, 2019, the Company entered into a Securities Purchase Agreement (the "Purchase Agreement") with certain purchasers who are parties to the Purchase Agreement (the "Purchasers"), pursuant to which the Company offered to the Purchasers, in a registered direct offering, an aggregate of (i) 1,040,000 shares (the "Shares") of common stock, par value $0.001 per share ("Common Stock") and (ii) pre-funded warrants to purchase 509,000 shares of Common Stock (the "Pre-Funded Warrants"). The Pre-Funded Warrants will be exercisable beginning on March 7, 2019 at an exercise price of $0.001 per share. The Shares were sold at a price of $2.00 per share and the Pre-Funded Warrants were sold at a price of $1.999 per Pre-Funded Warrant, which represents the per share purchase price for the Shares less the $0.001 per share exercise price for each such Pre-Funded Warrant. Aggregate gross proceeds to the Company were approximately $3.1 million, before deducting fees to the placement agent and other estimated offering expenses payable by the Company. The Shares and Pre-Funded Warrants were offered by the Company pursuant to an effective shelf registration statement on Form S-3, which the Company originally filed with the Securities and Exchange Commission on September 27, 2018, and was declared effective on October 12, 2018 (File No. 333-227572).

In a concurrent private placement, the Company also sold to the Purchasers a warrant to purchase one share of the Company's Common Stock for each Share and Pre-Funded Warrant purchased in the offering, representing warrants to purchase up to 1,549,000 shares of the Company's Common Stock (the "Purchase Warrants"). The Purchase Warrants will be exercisable beginning on September 8, 2019 (the "Initial Exercise Date") at an exercise price of $2.25 per share and expire on the seven year anniversary of the Initial Exercise Date.

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution

The following table sets forth the fees and expenses, other than underwriting discounts and commissions, payable in connection with the registration of the common stock hereunder. All amounts are estimates except the SEC registration fee and the FINRA filing fee.

SEC registration fee	$	2,121
FINRA Filing Fee(1)	$	
Blue Sky Fees and Expenses(1)	$	
Printing and Engraving Expenses(1)	$	
Legal Fees and Expenses(1)	$	
Accounting fees and expenses(1)	$	
Transfer Agent and Registrar Fees and Expenses(1)	$	
Miscellaneous (1)	$	
Total offering expenses	$	

_____
(1) To be provided by amendment.

Item 14. Indemnification of Directors and Officers

Nevada law provides that a Nevada corporation may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed proceeding, except an action by or in the right of the corporation, by reason of the fact that such person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation or other enterprise, against expenses, including attorneys' fees, judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with the proceeding, if such person:

- is not liable for breach of his or her fiduciary duties to the corporation; or
- acted in good faith and in a manner which he or she reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful.

In addition, a Nevada corporation may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action by or in the right of the corporation to procure a judgment in its favor by reason of the fact that such person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation or other enterprise against expenses, including amounts paid in settlement and attorneys' fees actually and reasonably incurred by such person in connection with the defense or settlement of the action, if he or she:

- is not liable for breach of his or her fiduciary duties to the corporation; or
- acted in good faith and in a manner which he or she reasonably believed to be in or not opposed to the best interests of the corporation.

Under Nevada law, indemnification may not be made for any claim as to which such a person has been adjudged by a court of competent jurisdiction, after exhaustion of all appeals therefrom, to be liable to the corporation or for amounts paid in settlement to the corporation, unless and only to the extent that a court of competent jurisdiction determines that in view of all the circumstances of the case, the person is fairly and reasonably entitled to indemnity for such expenses as the court deems proper.

To the extent that a director, officer, employee or agent of a corporation has been successful on the merits or otherwise in defense of any non-derivative proceeding or any derivative proceeding, or in defense of any claim, issue or matter therein, the corporation shall indemnify such person against expenses, including attorneys' fees, actually and reasonably incurred in connection with the defense.

Further, Nevada law permits a Nevada corporation to purchase and maintain insurance or to make other financial arrangements on behalf of any person who is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation or other enterprise for any liability asserted against him or her and liability and expenses incurred by him or her in his or her capacity as a director, officer, employee or agent, or arising out of his or her status as such, whether or not the corporation has the authority to indemnify such person against such liability and expenses.

Under our charter and bylaws, we are obligated to indemnify any director, officer, employee or agent of the company to the fullest extent permitted by the NRS, as described above. We have entered into separate indemnification agreements with our directors and executive officers, in addition to the indemnification provided for in our charter and bylaws. These agreements, among other things, require us to indemnify our directors and executive officers who have met the standards of conduct that make it permissible under the NRS for us to indemnify the claimant for certain expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by such person in any action or proceeding arising out of their services as one of our directors, officers, employees or agents, or any of our subsidiaries or any other company or enterprise to which the person provides services at our request. We believe that these charter and bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors.

In addition, indemnification is required to continue as to a person who has ceased to be a director or officer and inures to the benefit of his or her heirs, executors and administrators. Subject to the exceptions detailed below, we may indemnify a person seeking indemnification in connection with a proceeding (or part thereof) initiated by the person seeking indemnification only if the proceeding (or part thereof) was authorized by our board of directors. We may indemnify any employee or agent of us to an extent greater than required by law only if and to the extent that our directors, in their discretion, may determine.

If we do not pay a claim for indemnification within 60 days after a written claim has been received by us or pay an advancement of expenses under our bylaws in full within 20 days after a written claim has been received by us, the claimant may bring suit against us to recover the unpaid amount of the claim and, if successful in whole or in part, the claimant also will be entitled to be paid the expense of prosecuting such claim to the fullest extent permitted by applicable law. In any such action, we would have the burden of proving that the claimant is not entitled to the requested indemnification or advancement of expenses.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that in the opinion of the SEC this indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Item 15. Recent Sales of Unregistered Securities

March 2019

On March 5, 2019, we entered into a Securities Purchase Agreement (the "Purchase Agreement") with certain purchasers who are parties to the Purchase Agreement (the "Purchasers"), pursuant to which we sold to the Purchasers warrants to purchase up to 1,549,000 shares of the Common Stock (the "Purchase Warrants"). The Purchase Warrants will be exercisable beginning on September 8, 2019 (the "Initial Exercise Date") at an exercise price of $2.25 per share and expire on the seven year anniversary of the Initial Exercise Date.

The Purchase Warrants and the shares of common stock underlying the Purchase Warrants (the "Purchase Warrant Shares") have not been registered under the Securities Act, and instead are being offered pursuant to the exemption provided in Section 4(a)(2) under the Securities Act and Rule 506(b) promulgated thereunder. The Company has agreed to file a registration statement to register the resale of the Purchase Warrant Shares within 90 days of the date of the Purchase Agreement and to obtain effectiveness of such registration statement within 181 days following the closing of the offering. Each Purchaser is an "accredited investor" as defined in Rule 501(a)(1), (a)(2), (a)(3), (a)(7) or (a)(8) under the Securities Act.

September 2016

In September 2016, the Company issued 22,286 shares of the Company's common stock to non-employee consultants in exchange for services provided to the Company. The Company recorded $80,000 as the aggregate amount of consideration received by the Company for the associated services.

The shares were not registered under the Securities Act, or the securities laws of any state, and were offered and sold in reliance on the exemption from registration afforded by Section 4(a)(2) and Regulation D (Rule 506) under the Securities Act and corresponding provisions of state securities laws, which exempt transactions by an issuer not involving any public offering.

Also in September 2016, the Company issued 211,486 shares of common stock to Serum Institute in exchange for services and supply of research and development supply material. The aggregate value of the related goods and services was $913,000, of which $750,000 was recorded on the accompanying consolidated balance sheet as a prepayment as of December 31, 2016.

This issuance was made by the Company pursuant to an exemption from the registration either (a) under the Securities Act generally, in that the transactions are between an issuer and sophisticated investors and do not involve any public offering within the meaning of Section 4(a)(2) or (b) under Regulation S promulgated under the Securities Act in that offers, sales and issuances are not made to persons in the United States and no directed selling efforts are made in the United States.

Also in September 2016, the Company issued a $322,000 10% Senior Secured Collateralized Convertible Promissory Note plus a warrant to purchase 32,526 shares of common stock to Pharmsynthez. The gross proceeds of $322,000 were used for general working capital needs of the Company

This issuance was made by the Company pursuant to an exemption from the registration either (a) under the Securities Act generally, in that the transactions are between an issuer and sophisticated investors and do not involve any public offering within the meaning of Section 4(a)(2) or (b) under Regulation S promulgated under the Securities Act in that offers, sales and issuances are not made to persons in the United States and no directed selling efforts are made in the United States.

August 2016

In August 2016, we issued a $178,000 10% Senior Secured Collateralized Convertible Promissory Note plus a warrant to purchase 17,980 shares of common stock to Pharmsynthez. The gross proceeds of $178,000 were used for general working capital needs of the Company

This issuance was made by the Company pursuant to an exemption from the registration either (a) under the Securities Act generally, in that the transactions are between an issuer and sophisticated investors and do not involve any public offering within the meaning of Section 4(a)(2) or (b) under Regulation S promulgated under the Securities Act in that offers, sales and issuances are not made to persons in the United States and no directed selling efforts are made in the United States.

July 2016

On July 1, 2016, we issued a convertible promissory note in the amount of $369,957.51 and warrants to purchase 37,369 shares of our common stock at the exercise price to Mr. Maguire for his deferred salary. We also entered into a Deferred Salary Security Agreement with Mr. Maguire, pursuant to which Mr. Maguire agreed to continue to defer fifty percent (50%) of his salary until the earlier to occur of: (i) the closing of a public offering of our securities concurrent to a NASDAQ listing, or (ii) September 30, 2016 (the “Deferral End Date”).

Pursuant to the transactions contemplated by the Deferred Salary Security Agreement, the Company issued to M. Scott Maguire, a convertible promissory note (the “Note”) in the amount of $369,957.51 and warrants (the “Warrants”) to purchase 37,369 shares of the Company’s common stock at a price per share equal to the lesser of $6.60 and 120% of the price per share in the Company’s next capital raise of at least $15 million (the “Exercise Price”) for deferred salary. Further, effective July 1, 2016, the Company issued to PJSC Pharmsynthez, a convertible promissory note in the amount of $500,000 (the “Further Note”) and warrants to purchase 50,505 shares of the Company’s common stock at the Exercise Price (the “Further Warrants”) to PJSC Pharmsynthez, pursuant to Section 6.12 of the Asset Purchase Agreement, dated November 13, 2015, by and between the Company and Pharmsynthez, among others.

The Note and Warrants were issued in consideration for Mr. Maguire entering into the Deferred Salary Security Agreement. The Further Note and Further Warrants were issued in consideration for Pharmsynthez loaning $500,000 to the Company.

This issuances were made by the Company pursuant to an exemption from the registration either (a) under the Securities Act generally, in that the transactions are between an issuer and sophisticated investors and do not involve any public offering within the meaning of Section 4(a)(2) or (b) under Regulation S promulgated under the Securities Act in that offers, sales and issuances are not made to persons in the United States and no directed selling efforts are made in the United States.

April 2016

In April 2016, the Company issued 1,373,036 shares of the Company's common stock to Pharmsynthez in connection with the conversion of convertible promissory notes and related interest. In addition, the Company issued 3,045,455 shares of common stock to Pharmsynthez in connection with the completion of the XBIO-101 asset transfer.

This issuance was made by the Company pursuant to an exemption from the registration either (a) under the Securities Act generally, in that the transactions are between an issuer and sophisticated investors and do not involve any public offering within the meaning of Section 4(a)(2) or (b) under Regulation S promulgated under the Securities Act in that offers, sales and issuances are not made to persons in the United States and no directed selling efforts are made in the United States.

March 2016

In March 2016, the Company issued 19,858 shares of the Company's common stock to non-employee consultants in exchange for services provided to the Company. The Company recorded $203,000 as the aggregate amount of consideration received by the Company for the associated services.

The shares were not registered under the Securities Act, or the securities laws of any state, and were offered and sold in reliance on the exemption from registration afforded by Section 4(a)(2) and Regulation D (Rule 506) under the Securities Act and corresponding provisions of state securities laws, which exempt transactions by an issuer not involving any public offering.

Item 16. Exhibits and Financial Statement Schedules

(a) See Exhibit Index

(b) 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 included with this registration statement on Form S-1.

Item 17. Undertakings

Insofar as indemnification for liabilities arising under the Securities Act of 1933, as amended (the Act), may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is therefore unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue. The Registrant hereby undertakes that:

(a) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by section 10(a)(3) of the Securities Act of 1933;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement.

(b) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(c) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(d) That, for the purpose of determining liability of the registrant under the Securities Act of 1933 to any purchaser in the initial distribution of the securities: The undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

(i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;
(ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;
(iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and
(iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

(e) The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to section 13(a) or section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(f) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

(g) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(h) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

A list of exhibits filed with this registration statement on Form S-1 is set forth on the Exhibit Index below and is incorporated herein by reference.

EXHIBIT INDEX

Exhibit Number	Description
1.1	Form of Underwriting Agreement*
2.1	Share Purchase Agreement (Incorporated by reference to Exhibit 2.1 in the Company's Current Report on Form 8-K/A, filed on May 13, 2019). **†
3.1	Articles of Incorporation (Incorporated by reference to Exhibit 3.1 in the Company's Registration Statement on Form S-1, filed on November 21, 2011).
3.2	Certificate of Amendment to Articles of Incorporation (Incorporated by reference to Exhibit 3.1 in the Company's Current Report on Form 8-K, filed on February 12, 2013).
3.3	Certificate of Amendment to Articles of Incorporation (Incorporated by reference to Exhibit 3.1 in the Company's Current Report on Form 8-K, filed on February 27, 2013).
3.4	Certificate of Amendment to Articles of Incorporation (Incorporated by reference to Exhibit 3.1 in the Company's Quarterly Report on Form 10-Q, filed on January 10, 2014).
3.5	Certificate of Change Pursuant to NRS 78.209 (Incorporated by reference to Exhibit 3.2 in the Company's Quarterly Report on Form 10-Q, filed on January 10, 2014).
3.6	Certificate of Amendment to Articles of Incorporation (Incorporated by reference to Exhibit 3.1 in the Company's Current Report on Form 8-K, filed on September 30, 2015).
3.7	Amended and Restated Bylaws (Incorporated by reference to Exhibit 3.1 in the Company's Current Report on Form 8-K, filed on February 27, 2017).
3.8	Form of Amended and Restated Certificate of Designation of Preferences, Rights and Limitations of Series A Preferred Stock (Incorporated by reference to Exhibit 3.8 in the Company's Registration Statement on Form S-1/A, filed on October 27, 2016).
3.9	Second Amended and Restated Certificate of Designation of Preferences, Rights and Limitations of Series B Preferred Stock (Incorporated by reference to Exhibit 3.9 in the Company's Registration Statement on Form S-1/A, filed on October 31, 2016).
4.1	Form of Common Stock Certificate of the Registrant (Incorporated by reference to Exhibit 4.1 in the Company's Registration Statement on Form S-1/A, filed on July 14, 2016).
4.2	Xenetic Biosciences, Inc. Shareholder Voting Agreement dated October 26, 2016 between Xenetic Biosciences Inc. and SynBio, LLC(Incorporated by reference to Exhibit 4.2 in the Company's Registration Statement on Form S-1/A, filed on October 27, 2016).
4.3	SynBio LLC Warrant to Purchase Common Stock of Xenetic Bioscience, Incorporated(Incorporated by reference to Exhibit 10.2 in the Company's Annual Report on Form 10-K, filed on April 15, 2015).
4.4	Serum Institute of India Limited Warrant to Purchase Common Stock of Xenetic Bioscience, Incorporated(Incorporated by reference to Exhibit 10.03 in the Company's Annual Report on Form 10-K, filed on April 15, 2015).
4.5	Firdaus Jal Dastoor Warrant to Purchase Common Stock of Xenetic Bioscience, Incorporated(Incorporated by reference to Exhibit 10.04 in the Company's Annual Report on Form 10-K, filed on April 15, 2015).
4.6	Form of Common Stock Purchase Warrant (Incorporated by reference to Exhibit 10.3 in the Company's Current Report on Form 8-K, filed on November 16, 2015).
4.7	Form of Common Stock Purchase Warrant (Incorporated by reference to Exhibit 10.4 in the Company's Current Report on Form 8-K, filed on November 16, 2015).
4.8	Form of Amended and Restated Common Stock Purchase Warrant (Incorporated by reference to Exhibit 10.6 in the Company's Current Report on Form 8-K, filed on November 16, 2015).
4.9	Form of Common Stock Purchase Warrant (Incorporated by reference to Exhibit 10.3 in the Company's Current Report on Form 8-K, filed on July 8, 2016).
4.10	Form of Common Stock Purchase Warrant (Incorporated by reference to Exhibit 10.53 in the Company's Registration Statement on Form S-1/A, filed on October 31, 2016).
4.11	Form of Ten Percent (10%) Senior Secured Convertible Promissory Note(Incorporated by reference to Exhibit 10.2 in the Company's Current Report on Form 8-K, filed on November 16, 2015).
4.12	Form of Ten Percent (10%) Junior Secured Convertible Promissory Note – Due Deferral End Date(Incorporated by reference to Exhibit 10.2 in the Company's Current Report on Form 8-K, filed on July 8, 2016).
4.13	Form of Amended and Restated Ten Percent (10%) Senior Secured Convertible Promissory Note(Incorporated by reference to Exhibit 10.5 in the Company's Current Report on Form 8-K, filed on November 16, 2015).
4.14	Registration Rights Agreement, dated July 1, 2015, between Xenetic Bioscience, Inc. and OJSC Pharmsynthez(Incorporated by reference to Exhibit 10.3 in the Company's Current Report on Form 8-K, filed on July 8, 2015).
4.15	Form of First Amendment to Registration Rights Agreement (Incorporated by reference to Exhibit 10.8 in the Company's Current Report on Form 8-K, filed on November 16, 2015).
4.16	Form of Pre-Funded Warrant (Incorporated by reference to Exhibit 4.1 in the Company's Current Report on Form 8-K, filed on March 7, 2019).
4.17	Form of Purchase Warrant (Incorporated by reference to Exhibit 4.2 in the Company's Current Report on Form 8-K, filed on March 7, 2019).
5.1	Opinion of Westward Law, LLC*
10.1	OPKO Assignment Agreement (incorporated by reference to Exhibit 10.1 in the Company's Current Report on Form 8-K/A, filed on May 13, 2019). †
10.2	Voting Agreement - Pharmsynthez (Incorporated by reference to Exhibit 10.2 in the Company's Current Report on Form 8-K, filed on March 4, 2019).
10.3	Voting Agreement – OPKO (Incorporated by reference to Exhibit 10.3 in the Company's Current Report on Form 8-K, filed on March 4, 2019).
10.4	Voting Agreement – Dr. Genkin (Incorporated by reference to Exhibit 10.4 in the Company's Current Report on Form 8-K, filed on March 4, 2019).
10.5	Form of Securities Purchase Agreement (Incorporated by reference to Exhibit 10.1 in the Company's Current Report on Form 8-K, filed on March 7, 2019).
21.1	Subsidiaries (Incorporated by reference to Exhibit 21.1 to the Company's Annual Report on Form 10-K, filed on March 29 , 2019).
23.1	Consent of Marcum LLP
23.2	Consent of Westward Law, LLC (Included in Exhibit 5.1)*
24.1	Power of Attorney (included on signature page)
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	XRBL Taxonomy Extension Presentation Linkbase Document.

* To be filed by Amendment.

** Schedules and similar attachments to the Share Purchase Agreement, dated as of March 1, 2019, have been omitted pursuant to Item 601(b)(2) of Regulation S-K. The registrant hereby undertakes to furnish on a supplemental basis a copy of any omitted schedules and similar attachments to the Securities and Exchange Commission upon request.

† Certain portions of the exhibit have been omitted pursuant to Rule 601(b)(2) of Regulation S-K. The omitted information is not material and would likely cause competitive harm to the registrant if publicly disclosed.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the Registrant has duly caused this Registration Statement on Form S-1 to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Framingham, Commonwealth of Massachusetts, on the 15th day of May, 2019.

XENETIC BIOSCIENCES, INC.,
a Nevada corporation

By: /s/ Jeffrey F. Eisenberg
Name: Jeffrey F. Eisenberg
Title: Chief Executive Officer

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Jeffrey F. Eisenberg and James F. Parslow acting singly, his true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution for him and in his name, place and stead, in any and all capacities to sign any and all amendments including post-effective amendments to this registration statement, and any additional related registration statement filed pursuant to Rule 462(b) under the Securities Act of 1933, as amended (including post-effective amendments to this registration statement and any such related registration statements), and to file the same, with all exhibits thereto, and any other documents in connection therewith, granting unto said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his substitute, may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Jeffrey F. Eisenberg Jeffrey F. Eisenberg	Chief Executive Officer (Principal Executive Officer)	May 15, 2019
/s/ James Parslow James Parslow	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	May 15, 2019
/a/ James Callaway James Callaway	Director	May 15, 2019
/s/ Firdaus Jal Dastoor FCS Firdaus Jal Dastoor FCS	Director	May 15, 2019
/s/ Dmitry Genkin Dmitry Genkin	Director	May 15, 2019
/s/ Roman Knyazev Roman Knyazev	Director	May 15, 2019
/s/ Roger Kornberg Roger Kornberg	Director	May 15, 2019
/s/ Adam Logal Adam Logal	Director	May 15, 2019

Exhibit 23.1

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM'S CONSENT

We consent to the inclusion in this Registration Statement of Xenetic Biosciences, Inc. on Form S-1 of our report dated March 29, 2019, which includes an explanatory paragraph as to the Company's ability to continue as a going concern, with respect to our audits of the consolidated financial statements of Xenetic Biosciences, Inc. as of December 31, 2018 and 2017 and for each of the two years in the period ended December 31, 2018, which report appears in the Prospectus, which is part of this Registration Statement. We also consent to the reference to our Firm under the heading "Experts" in such Prospectus.

/s/ Marcum llp
Marcum llp
Boston, MA
May 15, 2019