

**UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549**

FORM 10-Q

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

For the quarterly period ended **March 31, 2019**

TRANSITION REPORTS PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.

For the transition period from _____ to _____

Commission File Number: **001-37937**

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

Nevada
(State or other jurisdiction of
incorporation or organization)

45-2952962
(IRS Employer
Identification No.)

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

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

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

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

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

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

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

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

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

As of May 6, 2019, the number of outstanding shares of the registrant's common stock was 10,443,889.

XENETIC BIOSCIENCES, INC.
FORM 10-Q
THREE MONTHS ENDED MARCH 31, 2019

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PART 1 – FINANCIAL INFORMATION

ITEM 1 – FINANCIAL STATEMENTS

XENETIC BIOSCIENCES, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

	<u>March 31, 2019</u> (Unaudited)	<u>December 31, 2018</u>
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	<u>\$ 16,456,192</u>	<u>\$ 14,431,094</u>
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	<u>\$ 4,937,664</u>	<u>\$ 4,518,306</u>
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	<u>11,518,528</u>	<u>9,912,788</u>
Total liabilities and stockholders' equity	<u>\$ 16,456,192</u>	<u>\$ 14,431,094</u>

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	<u>(1,327,155)</u>	<u>(1,828,343)</u>
Other income (expense):		
Other income (expense)	(245)	5,398
Interest income	150	427
Total other income (expense)	<u>(95)</u>	<u>5,825</u>
Net loss	\$ (1,327,250)	\$ (1,822,518)
Deemed dividend	<u>(3,879,447)</u>	<u>—</u>
Net loss applicable to common stockholders	<u>\$ (5,206,697)</u>	<u>\$ (1,822,518)</u>
Basic and diluted loss per share	<u>\$ (0.54)</u>	<u>\$ (0.21)</u>
Weighted-average shares of common stock outstanding, basic and diluted	<u>9,681,222</u>	<u>8,717,541</u>

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		Additional Paid in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Treasury Stock	Total Stockholders' Equity
	Number of Shares	Par Value (\$0.001)	Number of Shares	Par Value (\$0.001)					
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	<u>2,774,394</u>	<u>\$ 2,774</u>	<u>10,767,774</u>	<u>\$ 10,766</u>	<u>\$ 171,093,279</u>	<u>\$ (154,560,845)</u>	<u>\$ 253,734</u>	<u>\$ (5,281,180)</u>	<u>\$ 11,518,528</u>

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		Additional Paid in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Treasury Stock	Total Stockholders' Equity
	Number of Shares	Par Value (\$0.001)	Number of Shares	Par Value (\$0.001)					
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	<u>3,090,742</u>	<u>\$ 3,090</u>	<u>9,041,426</u>	<u>\$ 9,040</u>	<u>\$ 165,656,106</u>	<u>\$ (147,755,655)</u>	<u>\$ 253,734</u>	<u>\$ (5,281,180)</u>	<u>\$ 12,885,135</u>

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.

XENETIC BIOSCIENCES, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

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 progesterin – 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	<u>\$ 3,498</u>	<u>\$ 4,956</u>

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
	<u>\$ 233,940</u>	<u>\$ 406,194</u>

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.

ITEM 2 – MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This report contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and Section 27A of the Securities Act of 1933, as amended. All statements contained in this Quarterly Report other than statements of historical fact, including statements regarding our future results of operations and financial position, our business strategy and plans, future revenues, projected costs, prospects and our objectives for future operations, are forward-looking statements. These forward-looking statements include, but are not limited to, statements concerning our plans to develop our proposed drug candidates; our expectations regarding the nature, timing and extent of clinical trials and proposed clinical trials including the timing of generating clinical data from these trials; our expectations regarding the timing for proposed submissions of regulatory filings, including but not limited to any Investigational New Drug (“IND”) filing or any New Drug Application; 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 Chimeric Antigen Receptor (“CAR”) T Cell technology; and the risk that the acquisition of the CAR T technology may not be completed on the terms or in the timeframe expected by the Company.

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.

The Management’s Discussion and Analysis of Financial Condition and Results of Operations (the “MD&A”) should be read together with our condensed consolidated financial statements and related notes included elsewhere in this Quarterly Report. This Quarterly Report, including the MD&A, contains trend analysis and other forward-looking statements. Any statements in this Quarterly Report that are not statements of historical facts are forward-looking statements. These forward-looking statements made herein are based on our current expectations, involve a number of risks and uncertainties and should not be considered as guarantees of future performance.

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

- 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 our Annual Report on Form 10-K and in subsequent filings we make with the Securities and Exchange Commission.

These factors are not necessarily all of the important factors that could cause actual results to differ materially from those expressed in the forward-looking statements in this Quarterly Report. Other unknown or unpredictable factors also could have material adverse effects on our future results, including, but not limited to, those discussed in the section titled “Risk Factors.” The forward-looking statements in this Quarterly Report are made only as of the date of this Quarterly Report, and we do not undertake any obligation to publicly update any forward-looking statements to reflect subsequent events or circumstances. We intend that all forward-looking statements be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995.

BUSINESS OVERVIEW

We are a biopharmaceutical company focused on the discovery, research and development of next-generation biological drugs and novel oncology therapeutics. Our 170+ patent portfolio covers next generation biological drugs and novel oncology drug therapeutics and provides protection for our current drug candidates and 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.

Our most advanced investigational drug candidate is oncology therapeutic XBIO-101 (sodium cridanimod) for the treatment of progesterin resistant endometrial cancer. We have exclusive rights to develop and commercialize XBIO-101 worldwide, except for specified countries in the Commonwealth of Independent States. XBIO-101 has been granted orphan drug designation by the United States (“U.S.”) Food and Drug Administration (“FDA”) for the potential treatment of progesterone receptor negative endometrial cancer in conjunction with progesterone therapy. Our Phase II trial for XBIO-101 commenced patient dosing 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 PolyXenTM, 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, the focus of our internal development efforts was limited in the first three months of 2019 to research and development of our primary product candidate XBIO-101 and preliminary development efforts associated with the XCART platform technology. We plan to research potential utilities for XBIO-101, alone or in combination, in immuno-oncology approaches and will continue to look for potential partnering and out-licensing opportunities for our additional platform technologies subject to adequate funding.

On March 1, 2019, we entered into an agreement to acquire the XCART technology platform, a novel CAR T technology engineered to target patient- and tumor-specific neoantigens. 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.

Going Concern

We incurred a net loss of approximately \$1.3 million for the three months ended March 31, 2019. We 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. 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 its business plan and continue as a going concern.

We believe that we have access to capital resources through possible public or private equity offerings, debt financings, corporate collaborations, related party funding, or other means. On March 7, 2019, we closed a \$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.

While these condensed consolidated financial statements have been prepared on a going concern basis, if we do not successfully raise additional working capital, there can be no assurance that we will be able to continue our operations and these conditions raise substantial doubt about our ability to continue as a going concern. Under such circumstances, we would have to further reduce the planned scale of, or possibly suspend, some or all of our pre-clinical development initiatives and clinical trials. In addition, we would have to continue to reduce our general and administrative and other operating expenses and delay or cease the purchase of clinical research services if and until we are 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 we be unable to continue as a going concern.

Critical Accounting Estimates

The preparation of our financial statements in conformity with U.S. generally accepted accounting principles (“GAAP”) requires management 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 management’s 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.

There has been no material change to our critical accounting estimates since those critical accounting estimates described in our 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.

RESULTS OF OPERATIONS

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:

Category of Expense	Quarter ended,	
	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.

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.

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.

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.

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.

Contractual Obligations and Commitments

As of March 31, 2019, there were no material changes in our contractual obligations and commitments from those disclosed in our 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. See Note 11 to our condensed consolidated financial statements for a summary of our lease commitments.

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.

Recent Accounting Standards

See Note 2 to the unaudited condensed consolidated financial statements in Part I, Item 1 of this Quarterly Report and Note 2 in our 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 for a discussion of recent accounting standards.

Critical Accounting Policies and Estimates

Our condensed consolidated financial statements are prepared in accordance with U.S. GAAP. The preparation of our condensed consolidated financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, revenue, costs and expenses. We base our estimates and assumptions on historical experience and other factors that we believe to be reasonable under the circumstances. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates. There have been no material changes in our critical accounting policies from those disclosed in our 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.

ITEM 3 – QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are not required to provide the information required by this Item because we are a “smaller reporting company” (as defined in Rule 12b-2 of the Exchange Act).

ITEM 4 – CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer (principal executive officer) and Chief Financial Officer (principal financial officer), evaluated the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) or 15d-15(e) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), as of the end of the period covered by this Quarterly Report.

Based on this evaluation, our management, including our Chief Executive Officer and Chief Financial Officer, concluded that as of the end of the period covered by this Quarterly Report, our disclosure controls and procedures are designed at a reasonable assurance level and are effective to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC’s rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the period covered by this Quarterly Report that would have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

ITEM 1 – LEGAL PROCEEDINGS

We are not currently subject to any material legal proceedings, nor, to our knowledge, is any material legal proceeding threatened against us. From time to time, we may be a party to certain legal proceedings, incidental to the normal course of our business. While the outcome of these legal proceedings cannot be predicted with certainty, we do not expect that these proceedings will have a material effect upon our financial condition or results of operations.

ITEM 1A – RISK FACTORS

There have been no material changes to the risk factors previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2019 filed with the SEC on March 29, 2019 as amended on April 30, 2019.

ITEM 2 – UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None.

ITEM 3 – DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4 – MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5 – OTHER INFORMATION

None.

ITEM 6 – EXHIBITS

The following exhibits are incorporated herein by reference or filed as part of this report.

EXHIBIT NUMBER	DESCRIPTION
2.1***#	Share Purchase Agreement (incorporated by reference to Exhibit 2.1 of the Registrant's Form 8-K filed with the SEC on March 4, 2019).
3.1	Articles of Incorporation (incorporated by reference to Exhibit 3.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-178082) filed with the SEC on November 21, 2011).
3.2	Certificate of Amendment to Articles of Incorporation (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 333-178082) filed with the SEC on February 12, 2013).
3.3	Certificate of Amendment to Articles of Incorporation (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 333-178082) filed with the SEC on February 27, 2013).

- 3.4 [Certificate of Amendment to Articles of Incorporation](#) (incorporated by reference to Exhibit 3.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 333-178082) filed with the SEC on January 10, 2014).
- 3.5 [Certificate of Change Pursuant to NRS 78.209](#) (incorporated by reference to Exhibit 3.2 to the Registrant's Quarterly Report on Form 10-Q (File No. 333-178082) filed with the SEC on January 10, 2014).
- 3.6 [Certificate of Amendment to Articles of Incorporation](#) (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 333-178082) filed with the SEC on September 30, 2015).
- 3.7 [Amended and Restated Bylaws](#) (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-37937) filed with the SEC 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 of the Registrant's Registration Statement on Form S-1/A (File No. 333-211249) filed with the SEC 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 of the Registrant's Registration Statement on Form S-1/A (File No. 333-211249) filed with the SEC on October 31, 2016).
- 4.1 [Form of Pre-Funded Warrant](#) (incorporated by reference to Exhibit 4.1 of the Registrant's Form 8-K filed with the SEC on March 7, 2019).
- 4.2 [Form of Purchase Warrant](#) (incorporated by reference to Exhibit 4.2 of the Registrant's Form 8-K filed with the SEC on March 7, 2019).
- 10.1 [OPKO Assignment Agreement](#) (incorporated by reference to Exhibit 10.1 of the Registrant's Form 8-K filed with the SEC on March 4, 2019).
- 10.2 [Voting Agreement](#) – Pharmsynthez (incorporated by reference to Exhibit 10.2 of the Registrant's Form 8-K filed with the SEC on March 4, 2019).
- 10.3 [Voting Agreement](#) – OPKO (incorporated by reference to Exhibit 10.3 of the Registrant's Form 8-K filed with the SEC on March 4, 2019).
- 10.4 [Voting Agreement](#) – Dr. Genkin (incorporated by reference to Exhibit 10.4 of the Registrant's Form 8-K filed with the SEC on March 4, 2019).
- 10.5 [Form of Securities Purchase Agreement](#) (incorporated by reference to Exhibit 10.1 of the Registrant's Form 8-K filed with the SEC on March 7, 2019).
- 31.1* [Certification of Jeffrey F. Eisenberg, Principal Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.](#)
- 31.2* [Certification of James Parslow, Principal Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.](#)
- 32.1** [Certifications of Jeffrey F. Eisenberg, Principal Executive Officer, and James Parslow, Principal Financial Officer, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.](#)

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	XBRL Taxonomy Extension Presentation Linkbase Document

* Filed herewith.

** Exhibit 32.1 is being furnished and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section, nor shall such exhibits be deemed to be incorporated by reference in any registration statement or other document filed under the Securities Act of 1933, as amended or the Securities Exchange Act of 1934, as amended, except as otherwise stated in such filing 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.

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

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

XENETIC BIOSCIENCES, INC.

May 10, 2019

By: /S/ JEFFREY F. EISENBERG
Jeffrey F. Eisenberg
Chief Executive Officer
(Principal Executive Officer)

By: /S/ JAMES PARLOW
James Parslow
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

EXHIBIT 31.1

I, Jeffrey F. Eisenberg, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Xenetic Biosciences, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 10, 2019

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

EXHIBIT 31.2

I, James Parslow, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Xenetic Biosciences, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 10, 2019

By: /s/ James Parslow
James Parslow
Chief Financial Officer
(Principal Financial and Principal Accounting Officer)

EXHIBIT 32.1

CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the “Exchange Act”) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Jeffrey F. Eisenberg, Chief Executive Officer of Xenetic Biosciences, Inc. (the “Company”), and James Parslow, Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

The Company’s Quarterly Report on Form 10-Q for the period ended March 31, 2019, to which this Certification is attached as Exhibit 32.1 (the “Periodic Report”), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 10, 2019

In Witness Whereof, the undersigned have set their hands hereto as of the 10th day of May, 2019.

/s/ Jeffrey F. Eisenberg
Jeffrey F/ Eisenberg
Chief Executive Officer

/s/James Parslow
James Parslow
Chief Financial Officer

“This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Xenetic Biosciences, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.”