

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 September 30, 2018

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.)

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

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

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

As of November 5, 2018, the number of outstanding shares of the registrant's common stock was 9,403,889.

XENETIC BIOSCIENCES, INC.
FORM 10-Q
QUARTERLY PERIOD ENDED SEPTEMBER 30, 2018

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PART I – FINANCIAL INFORMATION

ITEM 1 – FINANCIAL STATEMENTS

**XENETIC BIOSCIENCES, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS**

	<u>September 30, 2018</u>	<u>December 31, 2017</u>
	<u>(Unaudited)</u>	
ASSETS		
Current assets:		
Cash	\$ 1,612,485	\$ 5,533,062
Restricted cash	66,510	66,510
Prepaid expenses and other	610,114	285,005
Total current assets	<u>2,289,109</u>	<u>5,884,577</u>
Property and equipment, net	8,243	27,846
Goodwill	3,283,379	3,283,379
Indefinite-lived intangible assets	9,243,128	9,243,128
Other assets	709,843	724,713
Total assets	<u>\$ 15,533,702</u>	<u>\$ 19,163,643</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 512,595	\$ 786,779
Accrued expenses	800,376	1,135,653
Other current liabilities	6,703	21,234
Total current liabilities	<u>1,319,674</u>	<u>1,943,666</u>
Deferred tax liability	2,918,518	2,918,518
Total liabilities	<u>\$ 4,238,192</u>	<u>\$ 4,862,184</u>
Commitments (Note 10)		
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 September 30, 2018 and December 31, 2017, respectively	1,804	2,120
Series A, \$0.001 par value: 970,000 shares issued and outstanding as of September 30, 2018 and December 31, 2017	970	970
Common stock, \$0.001 par value; 45,454,546 shares authorized as of September 30, 2018 and December 31, 2017; 9,727,774 and 9,041,426 shares issued as of September 30, 2018 and December 31, 2017, respectively; 9,403,889 and 8,717,541 shares outstanding as of September 30, 2018 and December 31, 2017, respectively		
	9,726	9,040
Additional paid in capital	167,904,823	165,249,912
Accumulated deficit	(151,594,367)	(145,933,137)
Accumulated other comprehensive income	253,734	253,734
Treasury stock	(5,281,180)	(5,281,180)
Total stockholders' equity	<u>11,295,510</u>	<u>14,301,459</u>
Total liabilities and stockholders' equity	<u>\$ 15,533,702</u>	<u>\$ 19,163,643</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		NINE MONTHS ENDED	
	SEPTEMBER 30,		SEPTEMBER 30,	
	2018	2017	2018	2017
Revenue				
Collaboration services	\$ —	\$ 85,000	\$ —	\$ 85,000
Total revenue	<u>—</u>	<u>85,000</u>	<u>—</u>	<u>85,000</u>
Operating costs and expenses:				
Cost of research and development revenue	—	(97,028)	—	(156,119)
Research and development	(735,879)	(884,797)	(2,369,219)	(2,979,778)
General and administrative	(1,079,008)	(1,343,671)	(3,267,597)	(4,948,675)
Loss from operations	<u>(1,814,887)</u>	<u>(2,240,496)</u>	<u>(5,636,816)</u>	<u>(7,999,572)</u>
Other income (expense):				
Other income (expense)	2,292	(14,979)	(24,838)	(49,611)
Interest income (expense)	59	(425)	424	8,732
Total other income (expense)	<u>2,351</u>	<u>(15,404)</u>	<u>(24,414)</u>	<u>(40,879)</u>
Net loss	<u>\$ (1,812,536)</u>	<u>\$ (2,255,900)</u>	<u>\$ (5,661,230)</u>	<u>\$ (8,040,451)</u>
Basic and diluted loss per share	<u>\$ (0.19)</u>	<u>\$ (0.26)</u>	<u>\$ (0.63)</u>	<u>\$ (0.93)</u>
Weighted-average shares of common stock outstanding, basic and diluted	<u>9,403,889</u>	<u>8,717,541</u>	<u>8,958,661</u>	<u>8,648,314</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)

	NINE MONTHS ENDED	
	SEPTEMBER 30,	
	2018	2017
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (5,661,230)	\$ (8,040,451)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	12,540	19,337
Gain on sale of property and equipment	(15,437)	–
Share-based payments	1,098,060	1,512,310
Warrant-based expense for services	24,940	(118,236)
Vendor share-based payments	52,281	97,781
Changes in operating assets and liabilities:		
Accounts receivable	–	2,957,500
Prepaid expenses and other assets	(310,239)	13,268
Accounts payable, accrued expenses and other liabilities	(623,992)	214,376
Net cash used in operating activities	<u>(5,423,077)</u>	<u>(3,344,115)</u>
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	<u>22,500</u>	<u>(9,264)</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of warrants	1,480,000	–
Net cash provided by financing activities	<u>1,480,000</u>	<u>–</u>
Net change in cash and restricted cash	(3,920,577)	(3,353,379)
Cash and restricted cash at beginning of period	<u>5,599,572</u>	<u>4,114,641</u>
Cash and restricted cash at end of period	<u>\$ 1,678,995</u>	<u>\$ 761,262</u>
SUPPLEMENTAL CASH FLOW INFORMATION:		
Cash paid for interest	<u>\$ 599</u>	<u>\$ 1,551</u>
SUPPLEMENTAL SCHEDULE OF NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Conversion of Series B preferred stock to common stock	<u>\$ 316</u>	<u>\$ 185</u>
Reclassification of common shares issuable to accounts payable	<u>\$ –</u>	<u>\$ 65,977</u>
Issuance of common stock for promissory note converted in 2016	<u>\$ –</u>	<u>\$ 125</u>

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 Lexington, Massachusetts, is a biopharmaceutical company focused on the discovery, research and development of next-generation biologic drugs and novel oncology therapeutics. Xenetic’s lead 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 uses 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 under development either in-house or with biotechnology and pharmaceutical industry collaborators to create what the Company believes will be the next-generation biologic drugs with improved pharmacological properties over existing therapeutics.

As used in this Quarterly Report on Form 10-Q (“Quarterly Report”), unless otherwise indicated, all references herein to “Xenetic,” the “Company,” “our,” “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 may be 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 \$5.7 million for the nine months ended September 30, 2018. The Company had an accumulated deficit of approximately \$151.6 million as of September 30, 2018 as compared to an accumulated deficit of approximately \$145.9 million at December 31, 2017. Working capital was approximately \$1.0 million as of September 30, 2018, and approximately \$3.9 million as of 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; 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 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 (“US GAAP”) 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, 2017 filed with the SEC on March 30, 2018 and amended on April 30, 2018.

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.

Recently Adopted Accounting Standards

New accounting standards which have been adopted

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

In November 2016, the FASB issued ASU 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash* that changes the presentation of restricted cash and cash equivalents on the statement of cash flows. Restricted cash and restricted cash equivalents 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 condensed consolidated statements of cash flows for the nine months ended September 30, 2017.

New accounting standards which have not yet been adopted

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 our condensed consolidated financial statements.

3. Significant Strategic Collaborations

The Company has entered into various research, development, license and supply agreements with Shire plc (“Shire”), Serum Institute of India (“Serum Institute”), its controlling stockholder PJSC Pharmsynthez (“Pharmsynthez”) and SynBio LLC (“SynBio”), which is now 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 September 30, 2018. No amounts were recognized as revenue related to these agreements during the nine months ended September 30, 2018 or 2017.

4. Property and Equipment, net

Property and equipment, net consists of the following:

	September 30, 2018	December 31, 2017
Laboratory equipment	\$ 234,845	\$ 264,583
Office and computer equipment	46,634	46,634
Leasehold improvements	26,841	26,841
Furniture and fixtures	20,263	20,263
Property and equipment – at cost	328,583	358,321
Less accumulated depreciation	(320,340)	(330,475)
Property and equipment – net	\$ 8,243	\$ 27,846

Depreciation expense was approximately \$1,000 and \$5,000 for the three months ended September 30, 2018 and 2017, respectively, and approximately \$13,000 and \$19,000 for the nine months ended September 30, 2018 and 2017, respectively. During the three months ended September 30, 2018, the Company sold lab equipment for \$22,500 resulting in an approximate \$15,000 gain.

5. 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 September 30, 2018 and December 31, 2017. No impairment was recorded during the nine months ended September 30, 2018 nor during the year ended December 31, 2017. OncoHist is not yet commercialized and, therefore, has not yet begun to be amortized as of September 30, 2018.

6. 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 nine months ended September 30, 2018 and September 30, 2017, respectively.

7. Stockholders' Equity

Common Stock

During the nine months ended September 30, 2018, 316,348 shares of Series B Preferred Stock were converted into 316,348 shares of common stock and 370,000 shares of common stock were issued as a result of the exercise of Class B warrants.

During the nine months ended September 30, 2017, 185,000 shares of Series B Preferred Stock were converted into 185,000 shares of common stock.

In March 2017, the Company issued 125,397 shares of the Company's common stock to Pharmsynthez, our controlling stockholder, in connection with the conversion by Pharmsynthez of its \$500,000, 10% convertible promissory note and related interest as a result of the Company's underwritten public offering in November 2016.

Warrants

During the nine months ended September 30, 2018, Class B warrants to purchase 370,000 shares of common stock were exercised resulting in approximately \$1.5 million of net proceeds to the Company. As of September 30, 2018, warrants to purchase an aggregate of 3,152,225 shares of common stock issued in connection with debt and equity financing arrangements were outstanding at a weighted average exercise price of \$4.33 and have expiration dates ranging from July 1, 2020 through November 2021.

8. Share-Based Compensation

Total share-based payments related to stock options, restricted stock units ("RSUs"), common stock awards, and non-financing warrants were \$0.3 million during both the three months ended September 30, 2018 and 2017, respectively, and \$1.2 million and 1.5 million for the nine months ended September 30, 2018 and 2017, respectively.

Share-based compensation expense is classified in the unaudited condensed consolidated statements of operations as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Research and development expenses	\$ 9,155	\$ 29,598	\$ 178,926	\$ 151,377
General & administrative expenses	314,323	272,393	996,355	1,340,478
	<u>\$ 323,478</u>	<u>\$ 301,991</u>	<u>\$ 1,175,281</u>	<u>\$ 1,491,855</u>

Employee Stock Options

No employee stock options or RSUs were granted nor exercised during the nine months ended September 30, 2018. During the nine months ended September 30, 2017, the Company granted 350,000 employee stock options. The key valuation assumptions used consisted of the Company's stock price, a risk-free rate of 0.19% and an expected volatility of approximately 110%. In addition, during the nine months ended September 30, 2017, the Company extended the exercise expiration date of certain former employee stock option awards resulting in a change in incremental value of approximately \$4,000, which was charged to administrative expense. The Company recognized a total of \$0.3 million of compensation expense related to employee stock options for both the three months ended September 30, 2018 and 2017, respectively, and \$1.1 million and \$1.4 million during the nine months ended September 30, 2018 and 2017, respectively.

Non-Employee Stock Options

During the nine months ended September 30, 2018, the Company granted 10,000 non-employee stock options. The key valuation assumptions used consisted of the Company's stock price, a risk-free rate of 1.70% and an expected volatility of 118.1%. No non-employee stock options were exercised during the nine months ended September 30, 2018. There were no non-employee stock options granted or exercised during the nine months ended September 30, 2017. The Company recognized approximately \$1,000 and \$36,000 of expense related to non-employee stock options during the three and nine months ended September 30, 2018, respectively, and approximately \$8,000 and \$80,000 of expense during the three and nine months ended September 30, 2017, respectively.

Common Stock Awards

During the three months ended September 30, 2018 and 2017, the Company granted 4,477 and 14,091 common stock awards, respectively, and 19,495 and 26,801 common stock awards during the nine months ended September 30, 2018 and 2017, 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 and \$38,000 of compensation expense related to common stock awards was recognized during the three months ended September 30, 2018 and 2017, respectively, and approximately \$52,000 and \$0.1 million during the nine months ended September 30, 2018 and 2017, respectively. The common stock awards were not issued as of September 30, 2018.

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 September 30, 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. The Company recognized a gain of approximately \$39,000 and \$22,000 related to collaboration and consulting warrants during the three months ended September 30, 2018 and 2017, respectively. For the nine months ended September 30, 2018 and 2017, the Company recognized expense of approximately \$25,000 and a gain of approximately \$0.1 million, respectively, related to collaboration and consulting warrants.

No collaboration or consulting service warrants were issued or exercised during the first nine months of 2018 and 2017. These warrants have expiration dates ranging from December 2019 through May 2021.

9. Income Taxes

During the nine months ended September 30, 2018 and 2017, 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 \$24.0 million and \$22.8 million as of September 30, 2018 and December 31, 2017, respectively.

As of September 30, 2018, and December 31, 2017, 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 September 30, 2018 and December 31, 2017, the Company did not record any unrecognized tax positions.

10. Commitments

In August 2013, the Company entered into an agreement to lease office and laboratory space in Lexington, Massachusetts under an operating lease with a commencement date of January 1, 2014 and a termination date of January 31, 2019. In connection with this lease, the Company is required to maintain a \$66,000 letter of credit as a security deposit. 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.

11. 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 year ended December 31, 2017 filed with the SEC on March 30, 2018, as amended on April 30, 2018.

12. 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 both historical and forward-looking statements as that term is defined under the Private Securities Litigation Reform Act of 1995 (“PSLRA”), Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). The forward-looking statements in this Quarterly Report are not based on historical facts, but rather reflect the current expectations of management concerning future results and events. These forward-looking statements include, but are not limited to, statements concerning our plans to continue the development of our proposed drug candidate; our expectations regarding the nature, timing and extent of clinical trials and proposed clinical trials, including the timing of generating clinical data from these trials; our expectations regarding the timing for proposed submissions of regulatory filings, including but not limited to any Investigational New Drug (“IND”) filing or any New Drug Application (“NDA”); the nature, timing and extent of collaboration arrangements; the expected results pursuant to collaboration arrangements including the receipts of future payments that may arise pursuant to collaboration arrangements; the outcome of our plans to obtain regulatory approval of our drug candidates; the outcome of our plans for the commercialization of our drug candidates; our plans to address certain markets, engage third party manufacturers, and evaluate additional drug candidates for subsequent commercial development, and the likelihood and extent of competition to our drug candidates.

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 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 further developing our primary drug candidate and to continue as a going concern;
- our ability to finance our business;
- product development and commercialization risks;
- 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; and
- other new lines of business that the Company may enter in the future.

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 have 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 PSLRA.

BUSINESS OVERVIEW

We are a biopharmaceutical company focused on the discovery, research and development of next-generation biologic drugs and novel oncology therapeutics. Our 170+ patent portfolio covers next generation biologic drugs and novel oncology drug therapeutics and provides protection for our current drug candidates and positions us well for strategic partnership and commercialization opportunities. The Company’s objective is to leverage its portfolio to maximize opportunities to out-license assets from its portfolio in order to generate working capital to both build long-term stockholder value and provide the Company with the funding necessary for clinical development of its oncology drug candidates through to market launch.

Our lead 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 (“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. Our Phase 2 trial for XBIO-101 commenced patient dosing in October 2017. We continue to experience slower progress in our Phase 2 trial than originally estimated, and therefore we are unable to predict when preliminary data from this trial may be available and we are evaluating our options with respect to the Phase 2 trial.

Our lead proprietary technology is PolyXen, an enabling platform technology which can be applied to protein or peptide therapeutics. It uses the natural polymer polysialic acid (“PSA”) to prolong a drug's circulating half-life and potentially improve other pharmacological properties. PolyXen has been demonstrated in human clinical trials to confer prolonged half-life on biotherapeutics such as recombinant human erythropoietin 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.

We continue to commit significant resources to our research and development activities and anticipate continuing to do so for the near future.

Going Concern

We had a net loss of approximately \$5.7 million for the nine months ended September 30, 2018, and had an accumulated deficit of \$151.6 million at September 30, 2018 as compared to an accumulated deficit of approximately \$145.9 million at December 31, 2017. Working capital was approximately \$1.0 million and \$3.9 million at September 30, 2018 and December 31, 2017, 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 our business plan and continue as a going concern.

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

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; 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.

Critical Accounting Estimates

The preparation of our financial statements in conformity with U.S. 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, 2017 filed with the SEC on March 30, 2018, as amended on April 30, 2018.

RESULTS OF OPERATIONS

Comparison of Quarter Ended September 30, 2018 and 2017

The comparison of our historical results of operations for the three months ended September 30, 2018 to the three months ended September 30, 2017 is as follows:

Description	Quarter Ended September 30, 2018	Quarter Ended September 30, 2017	Increase (Decrease)	Percentage Change
Revenue	\$ —	\$ 85,000	\$ (85,000)	(100.0)
Cost of research and development revenue	—	(97,028)	(97,028)	(100.0)
Research and development expenses	(735,879)	(884,797)	(148,918)	(16.8)
General and administrative expenses	(1,079,008)	(1,343,671)	(264,663)	(19.7)
Loss from operations	(1,814,887)	(2,240,496)	(425,609)	(19.0)
Other income (expense):				
Other income (expense)	2,292	(14,979)	(17,271)	(115.3)
Interest income (expense)	59	(425)	(484)	(113.9)
Net loss	<u>\$ (1,812,536)</u>	<u>\$ (2,255,900)</u>	<u>\$ (443,364)</u>	<u>(19.7)</u>

Revenue and Cost of Research and Development Revenue

There was no revenue and associated cost of research and development revenue during the three-months ended September 30, 2018. Revenue and cost of research and development revenue during the three months ended September 30, 2017 represented collaboration services related to research and development programs conducted on behalf of third parties.

Research and Development Expenses

Research and development (“R&D”) expenses decreased approximately \$0.1 million, or 16.8%, to \$0.7 million for the three months ended September 30, 2018 compared to the prior year period. The table below sets forth the R&D costs incurred by us, by category of expense, for the three months ended September 30, 2018 and 2017:

Category of Expense	Three Months Ended,	
	September 30, 2018	September 30, 2017
Outside services and contract research organizations	\$ 572,547	\$ 657,683
Salaries and wages	70,552	128,553
Share-based expense	9,155	29,598
Other	83,625	68,963
Total research and development expense	<u>\$ 735,879</u>	<u>\$ 884,797</u>

The decrease in outside services and contract research organizations for the three months ended September 30, 2018 compared to the prior year period was primarily due to our internal development efforts being limited to our lead product candidate, XBIO-101, due to capital constraints. Expense for the three months ended September 30, 2017 included costs associated with other development efforts but such costs were not continued in the current period as we exclusively focused on our XBIO-101 program in 2018. This decrease in costs was partially offset by increased spending on our XBIO-101 phase 2 clinical trial during the three months ended September 30, 2018 compared to the same period in the prior year. Salaries and wages decreased during the three months ended September 30, 2018 as we reduced our R&D headcount during the second half of fiscal year 2017 due to our limited internal development efforts.

General and Administrative Expenses

General and administrative expenses decreased by approximately \$0.3 million or 19.7% to \$1.1 million for the three months ended September 30, 2018, from \$1.3 million in the comparable quarter in 2017. Employee related costs, including payroll and travel, legal, accounting and insurance costs all decreased during the three months ended September 30, 2018 compared to the three months ended September 30, 2017 as we significantly reduced our discretionary spending due to our capital constraints. These decreases were partially offset by increases in share-based expense related to option grants and consulting costs as we replaced certain salaried positions with temporary employees in 2018.

Other Income (Expense)

Other income (expense) improved approximately \$17,000, or 115.3% to approximately \$2,000 of income for the three months ended September 30, 2018 compared to approximately \$15,000 of expense for the three months ended September 30, 2017. This improvement in other income (expense) is primarily due to changes in foreign currency exchange rates between the periods.

Interest Income (Expense)

Interest income (expense) was essentially break even for the three months ended September 30, 2018 compared to the three months ended September 30, 2017. Interest income on our cash balances offset interest expense associated with our leases.

Comparison of Nine Months Ended September 30, 2018 and 2017

The comparison of our historical results of operations for the nine months ended September 30, 2018 to the nine months ended September 30, 2017 is as follows:

Description	Nine Months Ended September 30, 2018	Nine Months Ended September 30, 2017	Increase (Decrease)	Percentage Change
Revenue	\$ —	\$ 85,000	\$ (85,000)	(100.0)
Cost of research and development revenue	—	(156,119)	(156,119)	(100.0)
Research and development expenses	(2,369,219)	(2,979,778)	(610,559)	(20.5)
General and administrative expenses	(3,267,597)	(4,948,675)	(1,681,078)	(34.0)
Loss from operations	(5,636,816)	(7,999,572)	(2,362,756)	(29.5)
Other income (expense):				
Other expense	(24,839)	(49,611)	(24,772)	(49.9)
Interest income, net	425	8,732	(8,307)	(95.1)
Net loss	<u>\$ (5,661,230)</u>	<u>\$ (8,040,451)</u>	<u>\$ (2,379,221)</u>	<u>(29.6)</u>

Revenue and Cost of Research and Development Revenue

There was no revenue and associated cost of research and development revenue during the nine months ended September 30, 2018. Revenue and cost of research and development revenue during the nine months ended September 30, 2017 represented collaboration services related to research and development programs conducted on behalf of third parties.

Research and Development Expenses

R&D expenses decreased \$0.6 million, or 20.5% to \$2.4 million for the nine months ended September 30, 2018 from \$3.0 million in the comparable period in 2017. The table below sets forth the R&D costs incurred by us by category of expense for the nine months ended September 30, 2018 and 2017:

Category of Expense	Nine Months Ended	
	September 30, 2018	September 30, 2017
Outside services and contract research organizations	\$ 1,765,209	\$ 2,139,004
Salaries and wages	207,794	448,828
Share-based expense	178,926	151,377
Other	217,290	240,569
Total research and development expense	<u>\$ 2,369,219</u>	<u>\$ 2,979,778</u>

The decrease in outside services and contract research organizations expense was primarily due to our internal development efforts being limited to our lead product candidate, XBIO-101, during the nine months ended September 30, 2018 due to capital constraints. Expense for the nine months ended September 30, 2017 included costs associated with other development efforts but such costs were not continued in the current period as we exclusively focused on our XBIO-101 program in 2018. This decrease in costs was partially offset by an increase in costs associated with our XBIO-101 phase 2 clinical trial during the nine months ended September 30, 2018 compared to the same period in the previous year. Salaries and wages decreased during the nine months ended September 30, 2018 as we reduced our R&D headcount in the second half of fiscal year 2017 due to our limited internal development efforts.

General and Administrative Expenses

General and administrative expenses decreased by approximately \$1.7 million or 34.0% to approximately \$3.3 million for the nine months ended September 30, 2018 from \$4.9 million in the comparable period in 2017. Employee related costs, including shared-based costs and travel, legal, accounting, and investor and public relations costs all decreased during the nine months ended September 30, 2018 compared to the nine months ended September 30, 2017 as we significantly reduced our discretionary spending due to our capital restraints.

Other Income (Expense)

Other expense decreased approximately \$25,000, or 49.9% to approximately \$25,000 for the nine months ended September 30, 2018 compared to approximately \$50,000 for the nine months ended September 30, 2017. This decrease is primarily related to changes in foreign currency exchange rates between the periods.

Interest Income (Expense)

Interest income, net decreased by approximately \$8,000, or 95.1%, to approximately \$1,000 for the nine months ended September 30, 2018 from approximately \$9,000 in the comparable period in the prior year. The decrease was primarily due to lower interest income during the nine months ended September 30, 2018 compared to the same period in the prior year.

Liquidity and Capital Resources

We incurred a net loss of approximately \$5.7 million for the nine months ended September 30, 2018, and had an accumulated deficit of \$151.6 million at September 30, 2018 as compared to an accumulated deficit of approximately \$145.9 million at December 31, 2017. Working capital was approximately \$1.0 million and \$3.9 million at September 30, 2018 and December 31, 2017, respectively. During the nine months ended September 30, 2018, our working capital decreased by \$2.9 million due primarily to outflows for general operating costs and costs related to our XBIO-101 phase 2 clinical trial. These cash outflows were partially offset by approximately \$1.5 million of proceeds received from the exercise of warrants during the nine months ended September 30, 2018. 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 September 30, 2018, we had approximately \$1.6 million in cash and \$1.3 million in accounts payable and accrued expenses. 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 \$60.0 million in proceeds from offerings of our common and preferred stock, including net proceeds of approximately \$9.0 million from our underwritten public offering in November 2016. We have also received approximately \$20.0 million from revenue producing activities from 2005 through September 30, 2018, including a cash payment from Shire of a \$3.0 million milestone payment in January 2017 and a \$7.5 million cash payment for a sublicense from Baxalta Incorporated, Baxalta US Inc., and Baxalta GmbH (collectively, with their affiliates, "Baxalta"), wholly-owned subsidiaries of Shire, in November 2017. More than 90% of the milestone and sublicense revenue received to date has been from a single collaborator, Shire. We expect the majority of our funding through equity or equity-linked instruments, debt financings and/or licensing agreements to continue as a trend for the foreseeable future.

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

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

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

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

Cash Flows from Operating Activities

Cash flows used in operating activities for the nine months ended September 30, 2018 totaled approximately \$5.4 million, which was primarily due to our \$5.7 million net loss for the period offset by non-cash charges of \$1.2 million, and approximately \$0.9 million of cash was used to reduce accounts payable and accrued expenses.

Cash flows used in operating activities for the nine months ended September 30, 2017 totaled approximately \$3.3 million, which was primarily due to our \$8.0 million net loss for the period offset by non-cash charges of \$1.5 million. This net use of cash was substantially offset by the receipt of the \$3.0 million clinical milestone payment from Shire in January 2017.

Cash Flows from Investing Activities

Cash flows provided by investing activities for the nine months ended September 30, 2018 totaled approximately \$23,000 which represented proceeds received from the sale of lab equipment.

For the nine months ended September 30, 2017, there were no significant cash sources or uses from investing activities.

Cash Flow from Financing Activities

Cash flows from financing activities for the nine months ended September 30, 2018 totaled approximately \$1.5 million representing proceeds from the exercise of warrants.

For the nine months ended September 30, 2017, there were no significant cash sources or uses from financing activities.

Contractual Obligations and Commitments

As of September 30, 2018, 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, 2017, filed with the SEC on March 30, 2018, as amended on April 30, 2018.

Off Balance Sheet Arrangements

We do not have any off-balance sheet financing arrangements that have or are reasonably likely to have a current or future material effect on our financial condition, change 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, 2017, filed with the SEC on March 30, 2018, as amended on April 30, 2018 for a discussion of recent accounting pronouncements.

Critical Accounting Policies and Estimates

Our condensed consolidated financial statements are prepared in accordance with generally accepted accounting principles in the United States or 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, 2017, filed with the SEC on March 30, 2018, as amended on April 30, 2018.

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 Securities Exchange Act of 1934, as amended (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 our 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 Exchange Act, as amended, as of the end of the period covered by this Quarterly Report.

Based on this evaluation, our management, including our Chief Executive Officer and our Chief Financial Officer, concluded that as of the end of the period covered by this Quarterly Report on Form 10-Q, 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, 2017, filed with the SEC on March 30, 2018, as amended on April 30, 2018.

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
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).
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

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.

November 9, 2018

By: /S/ Jeffrey F. Eisenberg

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

November 9, 2018

By: /S/ James Parslow

James Parslow
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

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: November 9, 2018

By: /s/ JEFFREY F. EISENBERG

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

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: November 9, 2018

By: /s/ JAMES PARSLOW

James Parslow
Chief Financial Officer
(Principal Financial and Principal Accounting Officer)

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 September 30, 2018, 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: November 9, 2018

In Witness Whereof, the undersigned have set their hands hereto as of the 9th day of November, 2018.

/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.”