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, 2016

☐ 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: 333-178082

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

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

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

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

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

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

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

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

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

As of November 14, 2016 the number of outstanding shares of the registrant's common stock was 8,288,644.

XENETIC BIOSCIENCES, INC.
FORM 10-Q
QUARTERLY PERIOD ENDED SEPTEMBER 30, 2016

PART 1 – FINANCIAL INFORMATION

ITEM 1 – FINANCIAL STATEMENTS

XENETIC BIOSCIENCES, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

	SEPTEMBER 30, 2016 (Unaudited)	DECEMBER 31, 2015
ASSETS		
Current assets:		
Cash	$ 211,896	$ 132,229
Restricted cash	66,510	66,510
Prepayment on acquisition	–	3,744,517
Prepaid expenses and other	930,685	247,298
Total current assets	1,209,091	4,190,554
Property and equipment, net	49,389	62,021
Goodwill	3,283,379	3,283,379
Indefinite-lived intangible assets	9,243,128	9,243,128
Other assets	81,060	129,306
Total assets	$ 13,866,047	$ 16,908,388
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,172,323	$ 1,788,521
Accrued expenses	1,488,929	1,487,046
Hybrid debt instrument, net	1,135,175	3,652,749
Other current liabilities	19,924	19,098
Loans due to related parties	152,529	395,000
Total current liabilities	4,968,880	7,342,414
Deferred tax liability	2,918,518	2,918,518
Other liabilities	24,733	38,791
Total liabilities	7,912,131	10,299,723
Stockholders' equity:		
Series A convertible preferred stock, $0.001 par value, 1,000,000 shares authorized, 970,000 and 0 shares issued and outstanding, with a liquidation preference of $4 and $0 as of September 30, 2016 and December 31, 2015, respectively	970	–
Common stock, $0.001 par value; 45,454,546 shares authorized as of September 30, 2016 and December 31, 2015; 8,612,529 and 4,909,685 shares issued as of September 30, 2016 and December 31, 2015, respectively; 8,288,644 and 4,585,800 shares outstanding as of September 30, 2016 and December 31, 2015, respectively	8,612	4,909
Additional paid in capital	152,918,456	99,763,101
Accumulated deficit	(141,946,676)	(88,131,899)
Accumulated other comprehensive income	253,734	253,734
Treasury stock	(5,281,180)	(5,281,180)
Total stockholders' equity	5,953,916	6,608,665
Total liabilities and stockholders' equity	$ 13,866,047	$ 16,908,388

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

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

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2016	**2015**	**2016**	**2015**
Operating costs and expenses:				
Research and development	$ 891,828	$ 816,318	$ 3,526,322	$ 2,407,141
IPR&D expense	–	–	39,500,000	–
General and administrative	1,359,801	2,984,484	4,339,844	4,723,109
Loss from operations	(2,251,629)	(3,800,802)	(47,366,166)	(7,130,250)
Non-operating income (expense):				
Change in fair value of derivative liability	241,298	(1,344,542)	2,146,587	(1,344,542)
Loss on issuance of hybrid debt instrument	(106,566)	–	(1,690,784)	(59,612)
Loss on conversion of debt	–	–	(6,187,337)	–
Other income (expense)	(13,440)	(50,526)	(26,991)	(216,429)
Interest income	4	67	31	1,155
Interest expense	(341,648)	(127,896)	(690,118)	(130,408)
Total non-operating expense, net	(220,352)	(1,522,897)	(6,448,612)	(1,749,836)
Net loss	(2,471,981)	(5,323,699)	(53,814,778)	(8,880,086)
Other comprehensive loss from foreign currency translation adjustment	–	5,112	–	(321,942)
Total comprehensive loss	$ (2,471,981)	$ (5,318,587)	$ (53,814,778)	$ (9,202,028)
Net loss per share of common stock, basic and diluted	$ (0.28)	$ (1.26)	$ (7.54)	$ (2.10)
Weighted-average shares of common stock outstanding, basic and diluted	8,987,145	4,228,974	7,134,352	4,223,905

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

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

	NINE MONTHS ENDED SEPTEMBER 30,	
	2016	**2015**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net Loss	$ (53,814,778)	$ (8,880,086)
Adjustments to reconcile net loss to net cash used in operating activities:		
IPR&D expense	39,500,000	–
Depreciation and amortization	27,246	47,472
Amortization of hybrid debt instrument discount	519,099	50,731
Non-cash interest expense	168,751	75,935
Share-based payments	1,518,344	1,875,891
Warrant expense for services	1,116,852	418,826
Change in fair value of derivative liability	(2,146,587)	1,344,542
Loss on issuance of hybrid debt instrument	1,690,787	59,612
Hybrid debt instrument issuance costs	(12,093)	(30,932)
Loss on conversion of debt	6,187,337	–
Foreign currency translation	–	346,386
Other non-cash transactions	40,611	(129,743)
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	43,682	50,459
Accounts payable, accrued expenses and other liabilities	997,500	585,681
Net cash used in operating activities	(4,163,249)	(4,185,226)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	(14,613)	(1,663)
Disposition of property and equipment	–	6,245
Net cash (used in) provided by investing activities	(14,613)	4,582
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of promissory note	4,500,000	3,100,000
Payments on loan from related party	(242,471)	(100,000)
Net cash provided by financing activities	4,257,529	3,000,000
Effect of exchange rate change on cash	–	(80,667)
Net change in cash, excluding restricted cash	79,667	(1,261,311)
Cash at beginning of period	132,229	2,507,401
Cash at end of period	$ 211,896	$ 1,246,090
SUPPLEMENTAL SCHEDULE OF NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Convertible debt paid in common stock	$ 6,500,000	$ –
Interest paid in common stock	$ 227,829	$ –
Non-cash issuance of warrants in connection with debt	$ 2,107,835	$ –
Non-cash recording of derivative liability in connection with debt	$ 4,120,359	$ –
Common stock exchanged for Series A convertible preferred stock	$ 970	$ –
Issuance of common stock for goods and services	$ 993,667	$ –

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

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

1. The Company

Background

Xenetic Biosciences, Inc. (the "Company"), incorporated in the state of Nevada and based in Lexington, Massachusetts, is a clinical stage biopharmaceutical company that is focused on the discovery, development and planned commercialization of a new generation of human drug therapies for the treatment of a variety of conditions including anemia, endometrial cancer, refractory Acute Myeloid Leukemia, Cystic Fibrosis and certain other cancers based upon its proprietary and patented drug delivery platform systems and drug development collaborations with major third party pharmaceutical companies around the world.

We incorporate our patented and proprietary technologies into a number of drug candidates currently under development either in-house or with biotechnology and pharmaceutical collaborators in order to create what we believe will be the next-generation biologic drugs and therapeutics. While we primarily focus on researching and developing orphan oncology drugs, we also have significant interests in drugs being developed by our collaborators to treat, among others, hemophilia and anemia. Our four core proprietary technologies are:

PolyXen™	An enabling biological platform technology designed to extend the circulation in the human body for a variety of existing drug molecules and, thereby, to create potentially superior next generation drug candidates. PolyXen is based on the concept of polysialylation and utilizes polysialic acid, or PSA, which is a biopolymer, comprising a chain of sialic acids molecules. PSA is a natural constituent of the human body, though we obtain our PSA from a bacterial source.
Virexxa®	A small molecule therapeutic with the potential to confer sensitivity to cancer cells to hormone therapeutics that are otherwise insensitive to such treatments. Virexxa, sodium cridanimod, belongs to a class of low-molecular weight synthetic interferon inducers. In addition to its immunomodulatory properties, Virexxa has been shown to increase levels of progesterone receptor expression in tumor tissue of patients who are progesterone receptor deficient, and thus may restore sensitivity of non-responsive endometrial cancers to hormonal (e.g., progestin) therapy. Based on preclinical observations, Virexxa may also be therapeutically relevant in other hormone-resistant cancers, such as triple-negative breast cancer. Virexxa has been granted an Orphan Drug Designation by the FDA, for treatment of progesterone receptor negative endometrial cancer in conjunction with progesterone therapy.
OncoHist™	A novel therapeutic platform technology that utilizes the properties of modified human histone H1.3 for targeted cell necrosis or apoptosis programed cell death, which may enable OncoHist to treat a broad range of cancer indications. OncoHist, unlike many competing oncology therapies, is based on a molecule occurring naturally in the human body, in the cell nucleus, and is therefore expected to be less toxic and immunogenic than other oncology therapies.
ImuXen™	A novel liposomal co-entrapment encapsulation technology designed to maximize both cell and immune system mediated responses. The technology is based on the co-entrapment of the nominated antigen(s) in a liposomal vesicle. The technology when applied may create new vaccines and improve the use and efficacy of certain existing human vaccines.

These proprietary technologies may address unmet needs, improve the performance of existing drugs, and create new patentable drug candidates. All of our drug candidates are in the development stage and none has yet received regulatory approval for marketing in the U.S. by the Food and Drug Administration ("FDA") or by any applicable agencies in other countries.

Going Concern and Management's Plan

While these condensed consolidated financial statements have been prepared on a going concern basis, conditions as of the balance sheet date raise substantial doubt about the Company's ability to continue as a going concern. As part of management's plan to address these conditions, on November 7, 2016, the Company issued $10 million of units consisting of Series B preferred stock and warrants, which management believes is sufficient to settle the Company's obligations and support operations for 12 months from issuance of these financial statements. See also Note 12 *Subsequent Events*.

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 2015 Annual Report on Form 10-K.

Reclassifications

Certain items previously reported in specific financial statement captions have been reclassified to conform to the current period presentation, including warrant expense in the condensed statements of cash flows and Note 8 *Share-Based Compensation.* Such reclassifications do not materially impact previously reported operating income (loss), net income (loss), total assets, liabilities or stockholders' equity (deficit).

Principles of Consolidation

The financial statements of the Company include the accounts of Xenetic Biosciences (UK) Limited ("Xenetic UK") and its wholly owned subsidiaries: Lipoxen Technologies Limited, Xenetic Bioscience, Incorporated, and SymbioTec GmbH ("SymbioTec"). All material intercompany balances and transactions have been eliminated on consolidation.

Recent Accounting Pronouncements

In March 2016, the FASB issued guidance to simplify several aspects of employee share-based payment accounting, including income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. This guidance will become effective for us beginning in the first quarter of 2017. Early adoption is permitted. We are currently evaluating the impact of the adoption of this standard.

There has been no other material changes to the recent accounting pronouncements under consideration since those described in our Annual Report on Form 10-K filed on March 30, 2016.

3. Significant Strategic Drug Development Collaborations – Related Parties

The Company has entered into various research, development, license and supply agreements with Shire plc ("Shire"), formerly Baxalta Incorporated (a spinoff of the biopharmaceuticals business from Baxter Healthcare SA and Baxter Healthcare Corporation), SynBio LLC ("SynBio"), Serum Institute of India ("Serum") and PJSC Pharmsynthez ("Pharmsynthez"). The Company and its collaborative partners continue to engage in research and development activities with no resultant commercial products through September 30, 2016. No amounts were recognized as revenue related to these agreements during the nine months ended September 30, 2016 or 2015.

4. Property and Equipment, net

Property and equipment, net consists of the following:

	September 30, 2016	December 31, 2015
Laboratory equipment	$ 264,583	$ 249,969
Office and computer equipment	35,190	35,190
Leasehold improvements	26,841	26,841
Furniture and fixtures	20,263	20,263
Property and equipment – at cost	346,877	332,263
Less accumulated depreciation	(297,488)	(270,242)
Property and equipment – net	$ 49,389	$ 62,021

Depreciation expense was $9,082 and $8,644 for the three months ended September 30, 2016 and 2015, respectively, and $27,246 and $40,107 for the nine months ended September 30, 2016 and 2015, respectively.

5. Hybrid Debt Instruments

On July 1, 2015, the Company entered into a Securities Purchase Agreement (the "SPA") with Pharmsynthez providing for the issuance of a minimum of a $3 million 10% Senior Secured Collateralized Convertible Promissory Note (the "SPA Note"). The SPA also provides for the issuance of certain warrants up to the amount of the SPA Note. The convertible debt and its embedded debt-like features were recorded on the face of the condensed consolidated balance sheet within current liabilities as an aggregate hybrid debt instrument.

On November 13, 2015, the Company entered into an Asset Purchase Agreement (the "APA") with Pharmsynthez providing for the issuance of a minimum of a $3.5 million 10% Senior Secured Collateralized Convertible Promissory Note (the "APA Note") and the transfer to the Company of certain intellectual property rights with respect to Virexxa in exchange for, among others, 111.5 million shares of our common stock. The APA also provides for the issuance of certain warrants covering up to half the amount of the APA Note. During the quarter ended March 31, 2016, the Company issued $3.5 million of convertible debt as well as the associated warrants, both in connection with the APA Note. The convertible debt and its embedded debt-like features were recorded on the face of the condensed consolidated balance sheet within current liabilities as an aggregate hybrid debt instrument.

On April 22, 2016, Pharmsynthez converted all convertible notes in the principal amount of $6.5 million plus accrued interest of approximately $228,000, issued by the Company to Pharmsynthez in 2015 and 2016. The conversion rate was $4.95 per share. As such, the Company issued to Pharmsynthez 1,373,036 shares of common stock in connection with conversion of the convertible notes. The related embedded derivatives, which had been bifurcated from the host debt and accounted for separately, were settled by action of the conversion. The Company recognized a net loss on conversion, including a final mark-to-market of the compound derivative, of $4.4 million, which is recorded in other expense in the condensed consolidated statement of comprehensive loss for the three and nine months ended September 30, 2016.

On July 1, 2016, the Company issued a convertible promissory note (the "Note") in the amount of $500,000 to Pharmsynthez, our majority shareholder. In consideration for the promissory note, we issued Pharmsynthez warrants (the "Warrants") to purchase 50,505 shares of our common stock at the lesser of $6.60 per share and 120% of the price per share in the Company's next capital raise of at least $15 million (the "Exercise Price"). The Note is convertible into shares of our common stock at any time at a conversion price of $4.95 per share (subject to price protection and usual and customary adjustments). The Warrants may be exercised at any time through the five-year anniversary. The maturity date of the Note is one year from issuance and is convertible, in whole or in part, into shares of common stock at the option of the holder, at any time and from time to time in accordance with the terms contained therein. Upon a public offering, as defined, the holder shall convert the Note to shares of the Company's common stock in accordance with the conversion terms contained therein.

Mr. M. Scott Maguire is our Chief Executive Officer. Mr. Maguire's current annual salary is $505,735 pursuant to his written employment agreement with the Company. Of Mr. Maguire's 2015 salary amount and 2016 salary amount through today, fifty percent (50%) has been paid in cash and fifty percent (50%) has been deferred and accrued pursuant to an unwritten arrangement between us and Mr. Maguire. On July 1, 2016, we issued a convertible promissory note (the "CEO Note") in the amount of $369,958 and warrants to purchase 37,369 shares of our common stock at the Exercise Price to Mr. Maguire for the deferred salary. The maturity date of the CEO Note is September 30, 2016. Upon a public offering, as defined, and at the option of the holder, the CEO Note may be settled in cash or by means of conversion into shares of common stock in accordance with the conversion terms contained therein.

On August 26 and September 9, 2016 we issued convertible promissory notes (the "Further Notes") in the amount of $178,000 and $322,000, respectively, and warrants to purchase 50,505 shares of our common stock at the Exercise Price to Pharmsynthez. The notes are convertible into shares of our common stock at any time at a conversion price of $4.00 per share (subject to price protection and usual and customary adjustments) or may be applied toward the Offering, at the option of Pharmsynthez. The maturity date of the Further Notes is one year from issuance and is convertible, in whole or in part, into shares of common stock at the option of the holder, at any time and from time to time in accordance with the terms contained therein. Upon execution of an underwriting agreement following declaration of effectiveness by the Securities and Exchange Commission of the registration statement filed in connection with the Company's contemplated public offering, the balance of the Further Notes shall automatically convert into units of the Company's contemplated public offering in accordance with the conversion terms contained therein.

The Note, CEO Note and Further Notes (together, the "Period Notes") share the same principal terms and features. The Period Notes are convertible debt and include embedded debt-like features which are recorded on the face of the condensed consolidated balance sheet within current liabilities as an aggregate hybrid debt instrument.

The fair value of the compound derivatives bifurcated from the Period Notes are remeasured at each report date until settled, with changes in fair value recognized in the consolidated statement of comprehensive loss as a gain or loss on derivative. Refer to Note 6 Fair Value Measurements for a table showing changes in the combined compound derivative during the nine months ended September 30, 2016.

The key assumptions used to calculate the estimated fair value of the compound derivative liability as of September 30, 2016, and as of December 31, 2015 are as follows:

	September 30, 2016	December 31, 2015
Company stock price	$ 4.50	$ 16.83
Expected volatility (%)	105%	105%
Risk-free interest rate (%)	0.52%	0.65%

Upon issuance of the Further Notes the offset to debt arising from the associated recording of the compound derivative liability, the warrants and the associated issuance costs exceeded the debt proceeds by $106,566. This amount was recorded as a loss in other expense in the condensed consolidated statement of comprehensive loss for the three months ended September 30, 2016.

Interest expense related to the SPA Note, the APA Note, and the Period Notes of approximately $341,000 and $690,000 was recognized in the condensed consolidated statement of comprehensive loss for the three and nine months ended September 30, 2016, respectively.

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

The following table provides a summary of the changes in fair value of the compound derivative measured at fair value on a recurring basis using significant unobservable inputs during the nine months ended September 30, 2016.

Balance as of January 1, 2016	$ 3,544,222
Issuances of compound derivative instruments	4,120,359
Change in fair value of compound derivative instruments	(2,146,587)
Settlement of derivative instruments through conversion of debt host	(4,985,356)
Balance as of September 30, 2016	$ 532,638

There were no financial instruments classified as Level 3 in the fair value hierarchy during the nine months ended September 30, 2015.

7. Stockholders' Equity

Reverse Stock Split

On May 16, 2016, our board of directors approved a reduction, on a 1 for 33 basis, in our authorized common stock, par value $0.001, along with a corresponding and proportional decrease in the number of shares issued and outstanding. This reduction was filed with the Nevada Secretary of State on May 18, 2016, but required a review by the Financial Industry Regulatory Authority, Inc. ("FINRA") before becoming effective in the market. On May 31, 2016, FINRA announced that this change took effect in the over-the-counter securities markets on June 1, 2016.

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

Common Stock

On April 29, 2016, the Company closed on the APA with an effective date of April 27, 2016, acquiring in-process research and development ("IPR&D") related to certain intellectual property rights with respect to the immunomodulator product Virexxa held by Kevelt including the grant of the worldwide right to develop, market and license Virexxa for certain uses. In connection with the closing of the APA, the Company issued 3.05 million shares of its common stock to Pharmsynthez and, because there was no alternative use for the IPR&D, the Company recognized $39.5 million of expense based on the fair value of Virexxa IP received, which was determined to be more reliably measured than the related equity consideration. Included in the $39.5 million expense was the $3.74 million prepayment recorded in 2015.

On September 15, 2016, the Company issued 211,486 shares of common stock to Serum in exchange for $750,000 of research and development ("R&D") and clinical PSA supply as well as settlement of prior purchases of PSA supply. Serum is a related party and the share transaction was approved by the Company's Board of Directors. Following the issuance and as of September 30, 2016, Serum's share ownership of the Company was approximately 7.6%.

On September 23, 2016, SynBio, one of our largest shareholders, exchanged 970,000 shares of common stock in the Company for an equal number of shares of Series A Preferred Stock.

Preferred Stock

As approved by the Company's Board of Directors, the Company filed with the Secretary of State of the State of Nevada a Certificate of Designation of Series A Preferred Stock on September 13, 2016, and subsequently filed an Amended and Restated Certificate of Designation of Series A Preferred Stock (the "Amended Series A Certificate of Designation"). Pursuant to the Amended Series A Certificate of Designation, the Company designated 1,000,000 shares as Series A preferred stock. Each share of Series A preferred stock has a stated value of $0.001 per share. In the event of a liquidation, dissolution or winding up of the Company, each share of Series A preferred stock will be entitled to a per share preferential payment equal to $4.80, the stated value. Each share of Series A preferred stock is convertible into one (1) share of common stock. The conversion ratio is subject to adjustment in the event of stock splits, stock dividends, combination of shares and similar recapitalization transactions. Except as otherwise provided in the Amended Series A Certificate of Designation or as otherwise required by law, the Series A has no voting rights.

As of September 30, 2015, there were 970,000 shares of Series A preferred stock issued and outstanding which are convertible into 970,000 shares of common stock.

Financing Warrants

In connection with the Company's issuance of the APA Note in March 2016, the Company issued a warrant to purchase 0.35 million shares of common stock in accordance with the terms of the APA (the "APA Warrant") at the Exercise Price. The APA Warrant has a five-year term and is exercisable commencing March 31, 2016. If the APA Note is not repaid or converted on or before six months from the date of issuance, the Holder will be issued an additional warrant to purchase 0.35 million shares of common stock under the same terms as the Warrant. At issuance the Company determined there was a low probability that the APA Note would not be repaid or converted within the period six months from the date of issuance and, therefore, did not account for the additional warrant as issued. (The APA Note was converted in April 2016.) The fair value of the warrant was calculated using the Black-Scholes option pricing model. Key valuation assumptions used consist of the Company's stock price, a risk free rate of 1.42% and an expected volatility of 135% and no expected dividends. Using an allocation of the APA Note proceeds between the relative fair values of the APA Warrant and the APA Note, the Company recorded the APA Warrant at a value of $1.7 million on the condensed consolidated balance sheet as equity paid-in-capital.

In connection with the Company's issuance of each of the Period Notes during the three months ended September 30, 2016, the Company issued warrants to purchase an aggregate of 138,379 shares of common stock at the Exercise Price and that are immediately exercisable. If the Period Notes are not repaid or converted on or before six months from the date of the respective issuances, the holders will be issued additional warrants to purchase 138,379 shares of common stock under the same terms as the immediately exercisable warrants. The Company has accounted for both sets of warrants (the "Period Warrants") as issued contemporaneous with the issuance of the associated debt instrument. The Period Warrants have five-year terms. The fair values of the Period Warrants were calculated using the Black-Scholes option pricing model. Key valuation assumptions used consist of the Company's stock price, risk free rates between 1.00% and 1.13% and expected volatilities of 110% and 120% and no expected dividends. Using allocations of the individual Period Note proceeds between the relative fair values of the individual Period Warrants and the Period Notes, the Company recorded the Period Warrants at an aggregate value of $0.41 million on the condensed consolidated balance sheet as equity paid-in-capital.

8. Share-Based Compensation

Total share-based compensation related to stock options, common stock awards, and non-financing warrants was $616,933 and $2,057,519 for the three months ended September 30, 2016 and 2015, respectively, and $2,635,196 and $2,294,717 for the nine months ended September 30, 2016 and 2015, respectively.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Research and development expenses	$ 113,976	$ 282,532	$ 1,348,216	$ 433,413
Administrative expenses	502,957	1,774,987	1,286,980	1,861,304
	$ 616,933	$ 2,057,519	$ 2,635,196	$ 2,294,717

Employee Stock Options

During the nine months ended September 30, 2016 and 2015, the Company granted 12,122 employee stock options. The key valuation assumptions used consisted of the Company's stock price, a risk free rate of 0.54% and an expected volatility of 123% and no expected dividends. There were no employee stock options granted during the same period in 2015. In March 2016, the Company extended the exercise expiration date of certain former employee stock option awards resulting in a change in incremental value of approximately $24,000 which was charged to administrative expense. In August 2016, the Company modified the exercise price and vesting of certain employee stock option awards resulting in a change in incremental value and catch up of share-based amortization of approximately $148,000 which was charged to administrative and research and development expense.

The Company recognized compensation expense related to employee stock options of $521,746 and $1,412,992 during the three months ended September 30, 2016 and 2015, respectively, and $1,311,074 and $1,497,295 during the nine months ended September 30, 2016 and 2015, respectively.

Non-Employee Stock Options

No non-employee stock options were granted during the nine months ended September 30, 2016 or 2015 and no non-employee stock options were exercised during the nine months ended September 30, 2016 or 2015. In August 2016, the Company modified the exercise price and vesting of certain non-employee stock option awards resulting in a change in incremental value and catch up of share-based amortization of approximately $17,000 which was charged to administrative expense. The Company recognized compensation expense related to non-employee stock options of $60,435 and $177,351 during the three months ended September 30, 2016 and 2015, respectively, and $62,938 and $186,544 during the nine months ended September 30, 2016 and 2015, respectively.

Common stock awards

The Company granted 8,146 and 371,292 common stock awards during the three months ended September 30, 2016 and 2015, respectively, and 20,309 and 605,580 common stock awards during the nine months ended September 30, 2016 and 2015, respectively, based on the value of the services provided and the average stock price during each respective period. The Company recognized compensation expense related to common stock awards of $36,542 and $116,045 during the three months ended September 30, 2016 and 2015, respectively, and $144,332 and $167,045 during the nine months ended September 30, 2016 and 2015, respectively.

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. On May 16, 2016, the Company modified the exercise price of 150,307 performance-based warrants held by Serum and individuals related to Serum from $25.41 to $7.92 and resulted in an incremental value expense of $204,000. Additionally, the Company issued 212,122 warrants to purchase shares of common stock to Serum with an exercise price of $7.92. The new warrants were fully vested and the Company recognized $1.37 million of expense related to the grant.

As of September 30, 2016, and December 31, 2015, warrants to purchase 758,347 shares of common stock were outstanding. These warrants were fair valued at each issuance date using the Black-Scholes option pricing model. Warrants for which a measurement date has not been reached 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. Expense for the nine months ended September 30, 2016, was $1.1 million including the incremental value recognized for the warrant modification. The Company issued no warrants in connection with collaboration agreements and consulting services during the three and nine months ended September 30, 2016.

The Company recognized warrant expense (gain) in connection with collaboration and consulting arrangements of ($1,790) and $326,123 during the three months ended September 30, 2016 and 2015, respectively, and $1,116,852 and $418,826 during the nine months ended September 30, 2016 and 2015, respectively.

9. Income Taxes

During the nine months ended September 30, 2016 and 2015, 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 $16.5 million and $15.3 million as of September 30, 2016 and December 31, 2015, respectively.

As of September 30, 2016, and December 31, 2015, the net deferred tax liability of $2,918,518 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 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, 2016 and December 31, 2015, 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. With the execution of this lease, the Company is required to maintain a $66,000 letter of credit as a security deposit. In connection with the Lexington lease, the Company recorded $68,742 as prepaid rent as of September 30, 2016, with $39,281 recorded as a non-current asset. The Company also incurred a liability of $89,074 with respect to the Company's contribution to the landlord's leasehold improvements, of which $43,707 is outstanding as of September 30, 2016, with $24,740 recorded as a non-current liability, respectively. This liability is repayable as additional rent expense over the term of the lease and bears interest at 6%. The Company also leased office space in London, UK during 2014, however the lease was terminated in March 2015 in accordance with the terms of the lease.

11. Related Party Transactions

In May 2011, the Company received a short term unsecured loan facility of up to $1.7 million from SynBio, an affiliate of the Company, of which $152,529 and $395,000 was outstanding as of September 30, 2016 and December 31, 2015, respectively. In connection with the APA, the Company made a series of payments during the first two quarters of 2016 totaling $242,471 to creditors of Kevelt. Pursuant to the APA such payments are considered direct offsets to the loan with SynBio. No payments were made during the nine months ended September 30, 2015. The loan had an interest rate of 8.04% per annum as of the date of grant, with interest payable upon repayment of the loan, which was to be seven months after the closing date of the loan. During 2012, the loan matured and it was agreed by both parties that the loan can be called due with full repayment of the outstanding principal including accrued interest upon future agreement by both parties. It was also agreed as of July 1, 2012 that no further interest on the outstanding loan balance would be accrued. The loan is recorded in "Loans due to related parties" within current liabilities.

The Company has entered into various research, development, license and supply agreements with Shire, SynBio, Serum and Pharmsynthez, each a related party whose relationship and ownership has not materially changed from that disclosed in our 10-K/A filed April 29, 2016.

12. Subsequent Events

As approved by the Company's Board of Directors, the Company filed with the Secretary of State of the State of Nevada a Certificate of Designation of Series B Preferred Stock on October 13, 2016, and subsequently filed a Second Amended and Restated Certificate of Designation of Series B Preferred Stock (the "Amended Series B Certificate of Designation"). Pursuant to the Amended Series B Certificate of Designation, the Company designated 2,500,000 shares as Series B preferred stock. Each share of Series B preferred stock has a stated value of $0.001 per share. In the event of a liquidation, dissolution or winding up of the Company, each share of Series B preferred stock will be entitled to a per share preferential payment equal to $4.00, the stated value. Each share of Series A preferred stock is convertible into one (1) share of common stock (i.e., an initial conversion price of $4.00). The conversion ratio is subject to adjustment in the event of stock splits, stock dividends, combination of shares and similar recapitalization transactions. In addition, subject to shareholder approval, if the Company issues or sells common stock or common stock equivalents entitling the grantee or purchaser to acquire shares of common stock at an effective price per share that is lower than the then applicable Series B conversion price (such lower price, the "Base Conversion Price"), the Series B conversion price will be reduced to the Base Conversion Price. Except as otherwise provided in the Amended Series B Certificate of Designation or as otherwise required by law, the Series B has no voting rights.

On November 7, 2016, the Company closed on an approximate $10 million underwritten public offering issuing 2,424,242 units (the "Units") at a purchase price of $4.125 per unit (the "Public Offering Close"). The Units sold consisted of (i) 484,849 shares of convertible Series B Preferred Stock (the "Shares") and a Class A Warrant (the "Class A Warrant") to purchase one share of the Company common stock, par value $0.001 per share (the "Common Stock") with an exercise price of $4.00 per warrant, and (ii) 1,939,393 shares of convertible Series B Preferred Stock (also, the "Shares") and a Class B Warrant (the "Class B Warrant" and together with the Class A Warrant, the "Warrants") to purchase one share of Common Stock, each with an exercise price of $4.00 per warrant.

Pursuant to the terms therein and in connection with the Public Offering Close, the balances of the Period Notes were settled as follows:

- The Note converted to shares of common stock
- The CEO Note was settled in cash
- The Further Notes converted into Units which are included in the aggregate 2,424,242 disclosed above.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This report contains both historical and forward-looking statements. The forward-looking statements in this quarterly report are not based on historical facts, but rather reflect the current expectations of our 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 candidates; our expectations regarding the nature, timing and extent of clinical trials and proposed clinical trials; our expectations regarding the timing for proposed submissions of regulatory filings, including but not limited to any Investigational New Drug ("IND") filing or any new drug application ("NDA"); the nature, timing and extent of collaboration arrangements; the expected results pursuant to collaboration arrangements including the receipts of future payments that may arise pursuant to collaboration arrangements; the outcome of our plans to obtain regulatory approval of our drug candidates; the outcome of our plans for the commercialization of our drug candidates; our plans to address certain markets, engage third party manufacturers, and evaluate additional drug candidates for subsequent commercial development, and the likelihood and extent of competition to our drug candidates.

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

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.

The single most pressing factor that could cause actual results to differ materially and adversely is our need to raise additional working capital for the purpose of further developing our various drug candidates.

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

- our ability to finance our business;
- our ability to achieve milestone and other payments associated with our co-development collaborations and strategic arrangements;
- the impact of new technologies on our drug candidates and our competition;
- changes in laws or regulations of governmental agencies;
- interruptions or cancellation of existing contracts;
- impact of competitive products and pricing;
- product demand and market acceptance and risks;
- the presence of competitors with greater financial resources;
- product development and commercialization risks;
- continued availability of supplies or materials used in manufacturing at the current prices;
- the ability of management to execute plans and motivate personnel in the execution of those plans;
- adverse publicity related to our products or the Company itself;
- adverse claims relating to our Intellectual Property ("IP");
- the adoption of new, or changes in, accounting principles;
- the costs inherent with complying with current and new 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. 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. Please also refer to risk factors described on SEC Form S-1 filed on May 9, 2016.

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

BUSINESS OVERVIEW

Management's discussion and analysis of our financial condition and results of operations ("MD&A") should be read in conjunction with the condensed consolidated financial statements and related footnotes.

The Company, carrying on business in a single operating segment, is a clinical-stage biopharmaceutical company focused on discovery, research and development of next-generation biologic drugs and novel orphan oncology therapeutics that may contribute to improvements in global human health. Our 200+ patent portfolio covers next generation biologic drugs and novel oncology therapeutics and provides protection for our current drug candidates and positions as well as strategic partnership and commercialization opportunities.

Our objective is to leverage our portfolio to maximize out-license opportunities that generate working capital to both build incremental shareholder value and provide funding necessary to clinically develop our orphan oncology drug candidate pipeline through to market launch.

Our lead product candidates include ErepoXen, a polysialylated form of erythropoietin (EPO) for the treatment of anemia in pre-dialysis patients with chronic kidney disease, and FDA orphan designated oncology therapeutics Virexxa and OncoHist for the treatment of progesterone receptor negative endometrial cancer and refractory Acute Myeloid Leukemia, respectively.

Significant Transactions and Recent Developments

Asset Acquisition and Financing Arrangements

On November 13, 2015, the Company entered into an Asset Purchase Agreement (the "APA") with Pharmsynthez providing for the issuance of a minimum of a $3.5 million 10% Senior Secured Collateralized Convertible Promissory Note (the "APA Note") and the transfer to the Company of certain intellectual property rights with respect to Virexxa in exchange for, among others, 111.5 million shares of our common stock. The APA also provides for the issuance of certain warrants covering up to half the amount of the APA Note. During the six months ended June 30, 2016, the Company issued $3.5 million of convertible debt as well as the associated warrants, both in connection with the APA Note. The convertible debt and its embedded debt-like features were recorded on the face of the consolidated balance sheet within current liabilities as an aggregate hybrid debt instrument.

On April 29, 2016, the Company closed on the APA with an effective date of April 27, 2016, acquiring certain intellectual property rights with respect to the immunomodulator product Virexxa held by Kevelt and grant of the worldwide right to develop, market and license Virexxa for certain uses.

In connection with the closing of the APA, the Company issued 3,045,455 shares of its common stock to Pharmsynthez. In addition, Pharmsynthez converted all convertible notes (in the principal amount of $6.5 million plus accrued interest of approximately $300,000), issued by the Company to Pharmsynthez in 2015 and 2016. The conversion rate as set forth in the notes was $4.95 per share. As such, the Company issued to Pharmsynthez 1,373,036 shares of its common stock in connection with conversion of the convertible notes, which amount, together with the 3,045,455 shares of common stock in connection with the closing of the Asset Purchase Agreement, resulted in an aggregate of 4,418,491 new shares of common stock being issued to Pharmsynthez.

On July 1, 2016, we issued a convertible promissory note (the "Note") in the amount of $500,000 to Pharmsynthez, our majority shareholder. In consideration for the promissory note, we issued Pharmsynthez warrants (the "Warrants") to purchase 50,505 shares of our common stock at the lesser of $6.60 per share and 120% of the price per share in the Company's next capital raise of at least $15 million. The Note is convertible into shares of our common stock at any time at a conversion price of $4.95 per share (subject to price protection and usual and customary adjustments). The Warrant may be exercised at any time through the five-year anniversary.

Mr. M. Scott Maguire is our Chief Executive Officer. Mr. Maguire's current annual salary is $505,735 pursuant to his written employment agreement with the Company. Of Mr. Maguire's 2015 salary amount and 2016 salary amount through today, fifty percent (50%) has been paid in cash and fifty percent (50%) has been deferred and accrued pursuant to an unwritten arrangement between us and Mr. Maguire. On July 1, 2016, we issued a convertible promissory note in the amount of $369,958 and warrants to purchase 37,369 shares of our common stock at the Exercise Price to Mr. Maguire for the deferred salary. We also entered into a Deferred Salary Security Agreement with Mr. Maguire, pursuant to which Mr. Maguire agreed to continue to defer fifty percent (50%) of his salary until the earlier to occur of: (i) the closing of a public offering of our securities concurrent to a NASDAQ listing, or (ii) September 30, 2016 (the "Deferral End Date"). All deferred salary shall become due and payable on the Deferral End Date. As security for the payment of the deferred salary, we granted Mr. Maguire a continuing subordinated security interest in our assets, including all inventory, accounts, accounts receivable, equipment, trademarks, contracts, copyrights and general intangibles.

On August 26 and September 9, 2016 we issued convertible promissory notes in the amount of $178,000 and $322,000, respectively, to Pharmsynthez. The notes are convertible into shares of our common stock at any time at a conversion price of $4.00 per share (subject to price protection and usual and customary adjustments) or may be applied toward the Offering, at the option of Pharmsynthez.

On September 23, 2016, SynBio LLC, one of our largest shareholders exchanged 970,000 shares of common stock in the Company for an equal number of shares of Series A Preferred Stock.

Technology Overview

We incorporate our patented and proprietary technologies into a number of drug candidates currently under development either in-house or with biotechnology and pharmaceutical collaborators in order to create what we believe will be the next-generation biologic drugs and therapeutics. While we primarily focus on researching and developing orphan oncology drugs, we also have significant interests in drugs being developed by our collaborators to treat, among others, hemophilia and anemia. Our four core proprietary technologies are:

PolyXen™ An enabling biological platform technology designed to extend the circulation in the human body for a variety of existing drug molecules and, thereby, to create potentially superior next generation drug candidates. PolyXen is based on the concept of polysialylation and utilizes polysialic acid, or PSA, which is a biopolymer, comprising a chain of sialic acids molecules. PSA is a natural constituent of the human body, though we obtain our PSA from a bacterial source.

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

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

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

These proprietary technologies may address unmet needs, improve the performance of existing drugs, and create new patentable drug candidates. All of our drug candidates are in the development stage and none has yet received regulatory approval for marketing in the U.S. by the FDA or by any applicable agencies in other countries.

Our Business Strategy

Our goal is to become a leader in the development of novel orphan oncology drugs while leveraging our proprietary delivery technology as a vehicle for creating next generation bio-therapeutics.

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

We advance our PolyXen platform technology through collaborative out-license arrangements with global pharmaceutical companies that can apply the resources necessary to bring the drug candidate to worldwide commercialization and with other partners that in-license our technology on a restrictive-market basis. The latter provides access to clinical data which can assist us in making decisions about potential monetization in larger markets.

We believe our orphan oncology drug candidates may meet an established and unmet therapeutic need for a relatively limited population of patients, and products with very high sales potential – benefiting from more favorable price and reimbursement policies.

We advance our drug candidates through a combination of conducting our own in-house research and through the use of contract manufacturing and contract research organizations in order to efficiently manage the Company's overheads. Continuous pipeline growth and advancement of out-licensed drug candidates is dependent, in part, on several important co-development collaborations and strategic arrangements. Together with our collaborative partners, we are focused on developing our pipeline of next generation bio-therapeutics and novel orphan drugs in oncology based primarily on our PolyXen, OncoHist and Virexxa proprietary technologies.

Critical Accounting Estimates

The preparation of our financial statements in conformity with US 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 amount of 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 could differ from our assumptions and estimates, and such differences could be material.

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 filed on March 30, 2016.

RESULTS OF OPERATIONS

Comparison of Quarter Ended September 30, 2016 and 2015

The comparison of our historical results of operations for the fiscal quarter ended September 30, 2016 to the fiscal quarter ended September 30, 2015 is set forth below:

Description	Quarter Ended September 30, 2016	Quarter Ended September 30, 2015	Increase (Decrease)	Percentage Change
Research and development expense	$ 891,828	$ 816,318	$ 75,510	9
General and administrative expense	1,359,801	2,984,484	(1,624,683)	(54)
Loss from operations	(2,251,629)	(3,800,802)	(1,549,173)	(41)
Other income (expense)	(13,440)	9,086	22,526	248
Change in fair value of derivative liability	241,298	(1,344,542)	(1,585,840)	(118)
Loss on issuance of debt	(106,566)	(59,612)	46,954	79
Interest income	4	67	63	94
Interest expense	(341,648)	(127,896)	213,752	167
Net loss	$ (2,471,981)	$ (5,323,699)	$ (2,851,718)	(54)

Research and Development

Overall, corporate R&D expenses for the quarter ended September 30, 2016 increased by $75,510, or 9% to $891,828 from $816,318 in the comparable quarter in 2015. The table below sets forth the R&D costs incurred by the Company, by category of expense, for the quarters ended September 30, 2016 and 2015:

	Quarter ended,	
Category of Expense	September 30, 2016	September 30, 2015
Outside services and Contract Research Organizations	$ 596,399	$ 365,679
Salaries and wages	115,283	112,284
Share-based compensation expense	113,976	282,532
Rent	23,777	21,796
Other	42,393	34,027
Total research and development expense	$ 891,828	$ 816,318

The increase in R&D expenses during the three months ended September 30, 2016, compared to the same period in 2015 was primarily due to the Company's initial scaling up of Virexxa clinical development. Share-based compensation expense fluctuated primarily due to the period-over-period remeasurement of warrants held by collaboration partners.

General and Administrative

General and administrative expenses decreased approximately $1.6 million or 54% for the quarter ended September 30, 2016 to $1,359,801 from $2,984,484 in the same quarter in 2015. The most significant drivers of the change were related to a decrease of approximately $724,000 and $287,000 in share-based expense and executive termination compensation, respectively, as well as an approximate $523,000 decrease legal, professional, and other consulting services.

Hybrid Debt Instrument

During the three months ended September 30, 2016 and 2015, the Company issued $1.37 million and $3.0 million in convertible promissory notes. The notes included embedded derivatives, which had been bifurcated from the host debt and accounted for separately, which required adjustments for changes in fair value over each period. The period adjustments were lower by approximately $1.6 million in the three months ended September 30, 2016, compared to the same period in 2015 due the lower face value of the instruments coupled changes in valuation inputs.

Comparison of Nine Months Ended September 30, 2016 and 2015

The comparison of our historical results of operations for the nine months ended September 30, 2016 to the nine months ended September 30, 2015 is set forth below:

Description	Nine Months Ended September 30, 2016	Nine Months Ended September 30, 2015	Increase (Decrease)	Percentage Change
Research and development	$ 3,526,322	$ 2,407,141	$ 1,119,181	47
IPR&D expense	39,500,000	–	39,500,000	–
General and administrative	4,339,844	4,723,109	(383,265)	(8)
Loss from operations	(47,366,166)	(7,130,250)	40,235,916	564
Other income (expense)	(26,991)	(216,429)	(189,438)	(88)
Change in fair value of derivative liability	2,146,587	(1,344,542)	(3,491,129)	(260)
Loss on issuance of hybrid debt instrument	(1,690,784)	(59,612)	1,631,172	2,736
Loss on conversion of debt	(6,187,337)	–	6,187,337	–
Interest income	31	1,155	1,124	97
Interest expense	(690,118)	(130,408)	559,710	429
Net loss	$ (53,814,778)	$ (8,880,086)	$ 44,934,692	506

Research and Development

Overall, corporate R&D expenses for the nine months ended September 30, 2016 increased by $40.6 million, or 1,687% to $43,026,322 from $2,407,141 in the comparable period in 2015. The table below sets forth the R&D costs incurred by the Company, by category of expense, for the nine months ended September 30, 2016 and 2015:

Category of Expense	Nine Months Ended, September 30, 2016	September 30, 2015
IPR&D expense	$ 39,500,000	$ –
Outside services and Contract Research Organizations	1,826,600	1,395,814
Salaries and wages	364,075	379,766
Share-based compensation expense	1,156,331	433,414
Rent	68,219	66,709
Other	111,097	131,438
Total research and development expense	$ 43,026,322	$ 2,407,141

The increase in R&D expenses during the nine months ended September 30, 2016, compared to the same period in 2015 was primarily due to the Company's acquisition and immediate expensing of the Virexxa asset ($39.5 million) coupled with $1.1 million recognized in connection with warrants issued to Serum. Separate from these, R&D costs were relative flat period over period.

General and Administrative

General and administrative expenses decreased by $0.4 million or 9% for the nine months ended September 30, 2016 to $4,339,844 from $4,723,109 in the comparable period of 2015. The most significant drivers of the change were a decrease of approximately $799,000 in personnel and share-based compensation expense offset by an increase in approximately $402,000 in outside consulting services.

Hybrid Debt Instrument

During the nine months ended September 30, 2016 and 2015, the Company issued $4.87 million and $3.0 million in convertible promissory notes. The notes included embedded derivatives, which had been bifurcated from the host debt and accounted for separately. Adjustments for changes in estimated fair value of the compound derivatives for the nine months ended September 30, 2016 was a gain of approximately $2.1 million compared to a $1.3 million loss in the same period of 2015. In April 2016, $6.5 million of the host debt instruments were converted to common shares which settled the associated compound derivatives.

Interest Expense

Interest expense increased by approximately $560,000 or 429% for the nine months ended September 30, 2016, to $690,118 from $130,408 in the comparable period 2015. The increase in interest expense is primarily due to interest charges associated with the SPA Note, APA Notes and Period Notes.

Liquidity and Capital Resources

At September 30, 2016 and December 31, 2015, we had working capital deficits of approximately $3.5 million and $3.2 million, respectively. At September 30, 2016 we had approximately $0.2 million in cash and $3.7 million in accounts payable and accrued expenses. At December 31, 2015, we had approximately $0.13 million in cash and $3.3 million in accounts payable and accrued expenses. Our working capital has increased in 2016 due primarily to $4.5 million of debt proceeds offset by $4.4 million net cash used during the nine months end September 30, 2016, which consisted of meeting creditor obligations, furthering our clinical development, and other general operating needs.

In November 2015 we entered into the APA which included the 1 st amendment to the SPA (the "Amended SPA") wherein Pharmsynthez agreed to purchase from the Company up to $3.5 million of additional 10% Convertible Promissory Notes (the "APA Notes"). The APA contains a total financing commitment from Pharmsynthez in the amount of $10 million. The APA Notes represent bridge financing to be drawn down from this $10 million. On July 1, 2016, the Company issued an additional $0.5 million note under APA, leaving a balance of $6.0 million in funding commitment from Pharmsynthez.

On November 7, 2016, the Company closed on an approximate $10 million underwritten public offering issuing 2,424,242 units (the "Units") at a purchase price of $4.125 per unit, which includes $6 million from Pharmsynthez. The Units sold consisted of (i) 484,849 shares of convertible Series B Preferred Stock (the "Shares") and a Class A Warrant (the "Class A Warrant") to purchase one share of the Company common stock, par value $0.001 per share (the "Common Stock") with an exercise price of $4.00 per warrant, and (ii) 1,939,393 shares of convertible Series B Preferred Stock (also, the "Shares") and a Class B Warrant (the "Class B Warrant" and together with the Class A Warrant, the "Warrants") to purchase one share of Common Stock, each with an exercise price of $4.00 per warrant.

We believe the proceeds from the November 7, 2016, sale of Units is sufficient to settle the Company's obligations and support operations for 12 months from issuance of these financial statements.

Until we reach commercialization of our technology or receive significant and regular cash flows from our current collaborations or from planned out-licensing of our technology, we expect the trend of accessing capital markets to finance our working capital needs to continue.

The only significant cash receipts that we could expect from our current collaborations would be from Shire. Due to the uncertainties and risks inherent in the clinical development process, we are unable to predict precisely when those receipts may occur, if ever. We do not expect any significant receipts to become due within the next five months. However, there can be no assurance that future receipts will ever become due because they are contingent on positive outcomes from Shire's clinical development efforts in connection with the Factor VIII drug candidate.

We have commenced the process of seeking out-license arrangements for our ErepoXen™ technology but are currently unable to reliably predict when that process may result in 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 Used in Operating Activities

Cash flows used in operating activities for the nine months ended September 30, 2016 totaled approximately $4.1 million, which includes a net loss of approximately $53.5 million offset by approximately $48.2 million in non-cash charges related to the Virexxa asset acquisition, which was immediately expensed ($39.5 million), as well as the hybrid debt instrument ($6.2 million including issuance loss, interest, amortization, change in fair value, and loss on extinguishment upon conversion of the debt host). In addition, as the Company recognized a net non-cash charge of approximately $2.6 million for share-based compensation and warrants.

Cash flows used in operating activities for the nine months ended September 30, 2015 totaled approximately $4.2 million, which includes a net loss of approximately $8.9 million These were partially offset by approximately $2.3 million in non-cash charges for share-based compensation, $1.3 million in charges related to the change in fair value of derivatives, $0.6 million in net decreases in receivables, other assets and increases in accounts payable and accrued expenses and approximately $0.3 million in foreign exchange translation charges. The $4.2 million includes cash expenses of approximately $1.3 million in professional fees, $1.1 million in salaries, employee fringe benefits and related taxes, including scientific staff, $0.8 million in program-specific clinical development costs, $0.2 million in rent and utilities expenses and $0.1 million in insurance costs.

Cash Flows from Investing Activities

For the nine months ended September 30, 2016 and 2015, respectively, there were no significant cash sources or uses from investing activities.

Cash Flow from Financing Activities

The Company received $4.5 million in proceeds from issuance of $4.5 million 10% convertible secured promissory notes in connection with the APA.

Off Balance Sheet Arrangements

The Company has no off balance sheet financing arrangements. The Company has one facility lease obligation and written employment agreements with three key employees as of September 30, 2016.

Recent Accounting Pronouncements

In March 2016, the FASB issued guidance to simplify several aspects of employee share-based payment accounting, including income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. This guidance will become effective for us beginning in the first quarter of 2017. Early adoption is permitted. We are currently evaluating the impact of the adoption of this standard.

There has been no other material changes to the recent accounting pronouncements under consideration since those described in our Annual Report on Form 10-K filed on March 30, 2016.

Available Information

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

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.

ITEM 4 – CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) 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 on Form 10-Q.

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 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 have been no changes in our internal control over financial reporting that occurred during the period covered by this Quarterly Report on Form 10-Q that 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 were no material changes to the risk factors described on SEC Form S-1 filed on May 9, 2016 (except to the extent additional factual information disclosed elsewhere in this Quarterly Report on Form 10-Q relates to such risk factors (including, without limitation, the matters discussed in Part 1, Item 2 – Management's Discussion and Analysis of Financial Condition and Results of Operations)).

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 attached list of exhibits in the "Exhibit Index" immediately preceding the exhibits to this Quarterly Report on Form 10-Q is incorporated herein by reference to this item.

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 14, 2016 By: /S/ MICHAEL SCOTT MAGUIRE

Michael Scott Maguire

Chief Executive Officer and President

EXHIBIT INDEX

EXHIBIT NUMBER	DESCRIPTION
31.1 *	Certification of Michael Scott Maguire, Principal Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2 *	Certification of Michael Scott Maguire, Principal Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1 **	Certifications of Michael Scott Maguire, Chief Executive Officer and Chief Financial Officer, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101 *	XBRL (eXtensible Business Reporting Language). The following materials from Xenetic Biosciences, Inc.'s Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2016, formatted in XBRL: (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Comprehensive Loss, (iii) the Condensed Consolidated Statements of Cash Flows, and (iv) Notes to Condensed Consolidated Financial Statements.

* Exhibit filed with this report

** 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 exhibit 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

EXHIBIT 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO EXCHANGE ACT RULES 13a-14(a) AND 15d-14(a),
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Michael Scott Maguire, 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 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 and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: November 14, 2016

By: /s/ Michael Scott Maguire
Michael Scott Maguire
Principal Executive Officer and President

EXHIBIT 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO EXCHANGE ACT RULES 13a-14(a) AND 15d-14(a),
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Michael Scott Maguire, 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 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 and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: November 14, 2016

By: /s/ Michael Scott Maguire
Michael Scott Maguire
Principal Financial Officer

EXHIBIT 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Xenetic Biosciences, Inc. (the "Company") on Form 10-Q for the quarter ended September 30, 2016, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), we, the undersigned officers of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of our knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

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

Dated: November 14, 2016

By: /s/ Michael Scott Maguire
Michael Scott Maguire
Chief Executive Officer and President