

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, 2015

**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**  
(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 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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>

(Do not check if a 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 16, 2015 the number of outstanding shares of the registrant's common stock was 150,513,011.

**XENETIC BIOSCIENCES, INC**  
**FORM 10-Q**  
**QUARTERLY PERIOD ENDED SEPTEMBER 30, 2015**

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**PART 1 – FINANCIAL INFORMATION**

**ITEM 1 – FINANCIAL STATEMENTS**

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

	<b>September 30, 2015 (Unaudited)</b>	<b>December 31, 2014</b>
<b>ASSETS</b>		
Current assets:		
Cash	\$ 1,246,090	\$ 2,507,401
Restricted cash	66,000	66,000
Other receivables	–	115,775
Prepaid expenses and other	195,194	88,237
Total current assets	<u>1,507,284</u>	<u>2,777,413</u>
Property and equipment, net	74,171	119,449
Goodwill	3,283,379	3,465,157
Indefinite-lived intangible assets	9,243,128	9,754,857
Other assets	145,883	199,270
Total assets	<u>\$ 14,253,845</u>	<u>\$ 16,316,146</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 1,484,890	\$ 852,760
Accrued expenses	1,381,394	1,409,691
Hybrid debt instrument	2,814,378	–
Other current liabilities	33,388	41,472
Loans due to related parties	395,000	395,000
Total current liabilities	<u>6,109,050</u>	<u>2,698,923</u>
Deferred tax liability	2,918,518	3,080,097
Other liabilities	43,270	56,383
Total liabilities	<u>9,070,838</u>	<u>5,835,403</u>
Commitments and contingent liabilities	–	–
Stockholders' equity:		
Common stock, \$0.001 par value; 1,500,000,000 and 215,456,000 shares authorized as of September 30, 2015 and December 31, 2014, respectively; 150,513,011 and 149,985,476 shares issued as of September 30, 2015 and December 31, 2014, respectively; 139,824,817 and 139,297,282 shares outstanding as of September 30, 2015 and December 31, 2014, respectively	150,513	149,989
Additional paid in capital	94,564,454	90,660,686
Accumulated deficit	(84,504,514)	(75,624,428)
Accumulated other comprehensive income	253,734	575,676
Treasury stock	(5,281,180)	(5,281,180)
Total stockholders' equity	<u>5,183,007</u>	<u>10,480,743</u>
Total liabilities and stockholders' equity	<u>\$ 14,253,845</u>	<u>\$ 16,316,146</u>

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

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

	<b>THREE MONTHS ENDED SEPTEMBER 30,</b>		<b>NINE MONTHS ENDED SEPTEMBER 30,</b>	
	<b>2015</b>	<b>2014</b>	<b>2015</b>	<b>2014</b>
Operating costs and expenses:				
Research and development	\$ (816,318)	\$ (1,905,234)	\$ (2,407,141)	\$ (3,502,805)
General and administrative	(2,984,484)	(1,203,126)	(4,723,109)	(5,204,541)
Loss from operations	<u>(3,800,802)</u>	<u>(3,108,360)</u>	<u>(7,130,250)</u>	<u>(8,707,346)</u>
Other income (expense):				
Change in fair value of derivative liability	(1,344,542)	–	(1,344,542)	–
Loss on disposal of subsidiaries	–	–	–	(1,069,675)
Other expense	(50,526)	(72,877)	(276,041)	(235,484)
Interest income	67	218	1,155	11,960
Interest expense	(127,896)	(1,196)	(130,408)	(3,569)
	<u>(1,522,897)</u>	<u>(73,855)</u>	<u>(1,749,836)</u>	<u>(1,296,768)</u>
Net loss	(5,323,699)	(3,182,215)	(8,880,086)	(10,004,114)
Other comprehensive income (loss) from foreign currency translation adjustment	<u>5,112</u>	<u>(542,098)</u>	<u>(321,942)</u>	<u>(18,457)</u>
Total comprehensive loss	<u>\$ (5,318,587)</u>	<u>\$ (3,724,313)</u>	<u>\$ (9,202,028)</u>	<u>\$ (10,022,571)</u>
Net loss per share of common stock, basic and diluted	<u>\$ (0.04)</u>	<u>\$ (0.02)</u>	<u>\$ (0.06)</u>	<u>\$ (0.07)</u>
Weighted-average shares of common stock outstanding, basic and diluted	<u>139,618,390</u>	<u>136,052,498</u>	<u>139,405,494</u>	<u>134,749,810</u>

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,	
	2015	2014
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net Loss	\$ (8,880,086)	\$ (10,004,114)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	47,472	59,108
Amortization of debt discount	50,731	–
Non-cash interest expense	75,935	–
Share-based compensation	2,294,717	678,508
Change in fair value of derivative liability	1,344,542	–
Loss on issuance of hybrid debt instrument	59,612	–
Hybrid debt instrument issuance costs	(30,932)	–
Loss on disposal of subsidiaries	–	1,069,675
Fee paid on disposal of subsidiaries	–	(430,000)
Foreign currency translation	346,386	(44,737)
Other non-cash transactions	(129,743)	–
Changes in operating assets and liabilities:		
Other receivables, prepayments and other assets	50,459	(160,983)
Accounts payable, accrued expenses and other liabilities	585,681	(1,186,034)
Net cash used in operating activities	<u>(4,185,226)</u>	<u>(10,018,577)</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchases of property and equipment	(1,663)	(46,009)
Disposition of property and equipment	6,245	5,487
Cash acquired from acquisition	–	43,502
Cash transferred in connection with Hive Out Agreement	–	(43,502)
Net cash provided by (used in) investing activities	<u>4,582</u>	<u>(40,522)</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from issuance of debt	3,100,000	–
Payments on debt	(100,000)	–
Proceeds from issuance of common stock	–	10,000,000
Proceeds from exercise of stock options	–	101,933
Payments on loan from related party	–	(286,124)
Net cash provided by financing activities	<u>3,000,000</u>	<u>9,815,809</u>
Effect of exchange rate change on cash	<u>(80,667)</u>	<u>238,444</u>
Net change in cash, excluding restricted cash	(1,261,311)	(4,846)
Cash at beginning of period	<u>2,507,401</u>	<u>4,839,486</u>
Cash at end of period	<u>\$ 1,246,090</u>	<u>\$ 4,834,640</u>
<b>SUPPLEMENTAL CASH FLOW INFORMATION:</b>		
Cash paid during the period for interest	\$ 592	\$ –
<b>SUPPLEMENTAL SCHEDULE OF NON-CASH INVESTING AND FINANCING ACTIVITIES:</b>		
Equity consideration transferred in the acquisition	<u>\$ –</u>	<u>\$ 3,750,000</u>
Repurchase and cancellation of common stock in disposal of subsidiaries	<u>\$ –</u>	<u>\$ (3,750,000)</u>

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, refractory Acute Myeloid Leukemia, Cystic Fibrosis and certain cancers based upon its proprietary and patented drug delivery platform systems, therapeutic drug candidates and drug development collaborations with major third party multinational pharmaceutical companies.

The Company’s drug delivery platform systems include PolyXen™ for creating next generation biologic drugs by extending the efficacy, safety and half-life of existing biologic drugs, OncoHist™ for the development of novel oncology drug therapies focused on orphan indications in humans and ImuXen™ for the development of vaccines that can simultaneously deliver multiple active pharmaceutical ingredients. The Company is also developing a broad pipeline of drug candidates for next generation biologics and novel oncology therapeutics in a number of orphan disease indications.

With the Company’s 2014 move to the United States from the United Kingdom, the Company is now focused on employing drug development expertise leveraging its 147 issued patents and 90 patent applications to create a proprietary pipeline of next generation product candidates. All the rights over the Company’s patents and licenses are controlled in the United Kingdom.

*Going Concern*

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. The accompanying condensed consolidated financial statements do not include any adjustments related to the recoverability or classification of asset-carrying amounts or the amounts and classification of liabilities that may result should the Company be unable to continue as a going concern.

**2. Summary of Significant Accounting Policies**

*Preparation of Interim Financial Statements*

The accompanying condensed consolidated financial statements were prepared by the Company pursuant to the rules and regulations of the Securities and Exchange Commission (“SEC”) and, in the opinion of management, include all normal and recurring adjustments necessary to present fairly the results of the interim periods shown. Certain information and footnote disclosures normally included in financial statements prepared in accordance with U.S. generally accepted accounting principles have been condensed or omitted pursuant to such SEC rules and regulations. Management believes that the disclosures made are adequate to make the information presented not misleading. The results for the interim periods are not necessarily indicative of results for the full year. The condensed consolidated financial statements contained herein should be read in conjunction with the consolidated financial statements and notes thereto included in the Company’s 2014 Annual Report on Form 10-K.

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

### ***Embedded Derivatives Related to Debt Instruments***

Embedded derivatives that are required to be bifurcated from their host contract are evaluated and valued separately from the host contract (i.e., the debt instrument). Features of the Company's debt instrument that meet the definition of a derivative and the criteria for separate accounting include the conversion feature and certain put options. Embedded derivatives are valued individually and recorded as a compound derivative. The compound derivative is presented together with the host debt instrument and the related debt discount on a combined basis. Changes in the estimated fair value of the bifurcated embedded derivatives are reported as gains and losses in the condensed consolidated statement of comprehensive loss.

### ***Correction of Identified Errors***

During the second quarter of 2015, the Company identified an error in the condensed consolidated financial statements related to the accounting for foreign currency matters. One of the Company's subsidiary's functional currency had been incorrectly designated as the Euro instead of British Pound Sterling during the period January 1, 2013 through March 31, 2015. As a result, certain applicable financial results of this entity were being translated to the reporting currency when they should have been first remeasured into the functional currency. In addition, the Company identified an error in the condensed consolidated financial statements related to the pushdown accounting of that subsidiary. The new basis of accounting of the acquired entity formed as a result of the acquisition was not first remeasured into the functional currency before being translated to the reporting currency.

The correction of the errors identified above resulted in the recognition of foreign currency net gains and foreign currency translation net losses. We concluded that these adjustments were not material to the Company's financial position or results of operations for the six months ended June 30, 2015 or any of the prior periods presented. Therefore, we recognized the cumulative impact during the three months ended June 30, 2015, which resulted in a net gain in other income (expenses) in the condensed consolidated statement of comprehensive loss of \$0.24 million for the nine months ended September 30, 2015 and a cumulative impact in accumulated other comprehensive income in the condensed consolidated balance sheet of \$0.31 million as of September 30, 2015.

### ***Principles of Consolidation***

The condensed consolidated financial statements of the Company include the accounts of Xenetic Biosciences (UK) Limited 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.

### ***Change in Accounting Principle***

During the second quarter of 2015, the Company elected to apply pushdown accounting to the Company's acquisition of SymbioTec that occurred in 2012. Pushdown accounting refers to the use of the acquirer's basis in the preparation of the acquiree's separate financial statements as the new basis of accounting for the acquiree. Application of pushdown accounting is treated as a change in accounting principle and was applied retrospectively to the Company's condensed consolidated financial statements. This change resulted in no impact to the condensed consolidated financial statements for the nine months ended September 30, 2015 or 2014.

### ***Functional Currency Change***

Effective April 1, 2015, the functional currency of the Company's foreign subsidiaries changed from the British Pound Sterling to the U.S. dollar. The changes in the economic facts and circumstances that caused the functional currency to change to that of the parent company include: the closing of the Company's last office outside of the U.S. during the first quarter of 2015, a shift of financial dependence of the subsidiaries to the parent, as well as the growth of the Company's operations in U.S. dollar-denominated expenses. The Company translated assets and liabilities of these foreign subsidiaries at the exchange rate in effect at the balance sheet date and included accumulated net translation adjustments in equity as a component of accumulated other comprehensive loss. The change in functional currency is applied on a prospective basis. Therefore, any gains and losses that were previously recorded in accumulated other comprehensive loss remain unchanged through March 31, 2015. Foreign currency transaction gains and losses are the result of exchange rate changes on transactions denominated in currencies other than the functional currency. The remeasurement of those foreign currency transactions is included in determining net income or loss for the period of exchange.

### Recent Accounting Pronouncements

In April 2015, Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2015-03, *Interest – Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs* (“ASU 2015-03”). ASU 2015-03 requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. This guidance is effective for annual reporting periods beginning after December 15, 2015, and interim periods within fiscal years beginning after December 15, 2016. The Company early adopted ASU 2015-03 in July 2015, as permitted. There was no impact of early adoption of ASU 2015-03 on the Company’s condensed consolidated financial statements previously reported.

In August 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2014-15, *Presentation of Financial Statements – Going Concern (Subtopic 205-40)* (“ASU 2014-15”). ASU 2014-15 defines management’s responsibility to evaluate whether there is substantial doubt about an organization’s ability to continue as a going concern and provides guidance on the related footnote disclosures. This guidance is effective for annual reporting periods beginning after December 15, 2016, and interim periods within annual periods beginning after December 15, 2016. Early application is permitted. The Company is currently evaluating the impact of this new standard.

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)* (“ASU 2014-09”). ASU 2014-09 supersedes the revenue recognition requirements in Accounting Standards Codification (“ASC”) Topic 605, *Revenue Recognition*, and most industry-specific guidance. The core principle of the guidance is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled to in exchange for those goods or services. In August 2015, the FASB issued ASU 2015-15, *Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date*, which defers the effective date of ASU 2014-09 for all entities by one year. This guidance is currently effective for annual reporting periods beginning after December 15, 2017, including interim periods within that reporting period, under either full or modified retrospective approach. Early application is permitted as of annual reporting periods beginning after December 15, 2016. The Company is currently evaluating the impact of this new standard on its revenue recognition policy.

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

### 3. Significant Strategic Drug Development Collaborations

The Company had various research, development, license and supply agreements with Baxter Healthcare SA and Baxter Healthcare Corporation (together referred to as “Baxter”). During June 2015, in connection with the separation of its biopharmaceuticals business to form Baxalta Incorporated (“Baxalta”), Baxter assigned all of its rights and obligations under its existing agreement with the Company to Baxalta. Other than, with respect to the assignment to Baxalta, the Company’s agreements with Baxter will continue with full force and effect. In addition, the Company has various research, development, license and supply agreements with SynBio LLC (“SynBio”), Serum Institute of India (“Serum Institute”) and OJSC Pharmsynthez (“Pharmsynthez”). The Company and its collaborative partners continued to engage in research and development activities with no resultant commercial products through September 30, 2015. No amounts were recognized as revenue related to these agreements during the nine months ended September 30, 2015 or 2014.

### 4. Property and Equipment, net

Property and equipment, net consists of the following:

	September 30, 2015	December 31, 2014
Laboratory equipment	\$ 255,813	\$ 254,150
Office and computer equipment	35,190	189,459
Leasehold improvements	26,841	92,354
Furniture and fixtures	20,263	50,150
Property and equipment – at cost	338,107	586,113
Less accumulated depreciation	(263,936)	(466,664)
Property and equipment – net	\$ 74,171	\$ 119,449

Depreciation expense was \$8,644 and \$23,254 for the three months ended September 30, 2015 and 2014, respectively, and \$40,107 and \$55,769 for the nine months ended September 30, 2015 and 2014, respectively.



## 5. Goodwill and Indefinite-Lived Intangible Assets

### *Goodwill*

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

Balance as of January 1, 2014	\$ 3,665,199
Foreign currency translation	(200,042)
Balance as of December 31, 2014	<u>3,465,157</u>
Foreign currency translation	(181,778)
Balance as of September 30, 2015	<u>\$ 3,283,379</u>

### *Indefinite-Lived Intangible Assets*

The Company's acquired indefinite-lived intangible asset, OncoHist™, is in-process research and development related to the Company's business combination with SymbioTec. The carrying value of OncoHist™ was \$9,243,128 and \$9,754,857 as of September 30, 2015 and December 31, 2014, respectively. No impairment was recorded during the nine months ended September 30, 2015 and 2014. The decrease in the carrying value during the reporting periods is solely comprised of the effects of changes in foreign currency.

## 6. Hybrid Debt Instrument

On July 1, 2015, the Company entered into a Securities Purchase Agreement (the "SPA") with Pharmsynthez (the "Holder") providing for the issuance of a minimum of a \$3 million 10% Senior Secured Collateralized Convertible Promissory Note (the "Note"). The SPA also provides for the issuance of certain warrants up to the amount of the Note. See Note 8, *Stockholders' Equity*, for discussion of the accounting treatment of the warrants. As explicated below, the convertible debt and its embedded debt-like features have been recorded on the face of the condensed consolidated balance sheet as an aggregate hybrid debt instrument with a balance of \$2.8 million as of September 30, 2015.

On July 1, 2015, the Company issued the Note for \$3 million plus a warrant to purchase 10 million shares of common stock in accordance with the terms of the SPA. The Note carries a term of one year and is convertible, in whole or in part, at the option of the Holder into shares of common stock at a conversion price of \$0.15. The Note bears interest at the rate of 10% annually, payable quarterly in cash or, at the Company's option, in shares of common stock at the lesser of \$0.15 or the then applicable conversion price. At any point after six months following the issuance of the Note, but before the maturity date of the Note, the Company has the option of prepayment of the Note and any accrued interest. If the Company exercises the prepayment option, the Company is obligated to pay the outstanding principal amount of the Note and accrued interest multiplied by 115%. If the Note is converted or redeemed, prior to the maturity date, the Company will pay cash to the Holder equal to the interest that would have accrued from the conversion or redemption date to the maturity date.

Upon a public offering in which the Company obtains financing of \$7 million or greater ("Public Offering"), the Holder has the option to either redeem the Note for cash at the balance of principal plus accrued interest multiplied by 115% or convert the principal plus accrued interest multiplied by 115% into common stock at the effective conversion price. In the event of default, as defined under the terms of the Note, all obligations will be immediately due and payable and the interest rate will increase to 18% annually. The Company determined these two features represent contingent put options for the Holder.

The Company concluded the two contingent put option features related to a public offering and event of default, the Note conversion feature and the ability for interest to be paid in shares of common stock feature each meet the definition of a derivative under ASC Topic 815, *Derivatives and Hedging* ("ASC 815"), and require bifurcation and accounting as embedded derivatives. The four embedded derivatives, which were bifurcated and individually fair valued by the Company, have been recorded as a compound derivative within the Hybrid Debt Instrument. The Company calculated the fair values of each individual embedded derivative by taking the difference between the fair value of the Note with each embedded derivative and the fair value of the Note without the individual embedded derivative. The Company calculated the fair values using the discounted present value of each embedded derivative value as determined by Monte Carlo Simulations. The key valuation assumptions used consist of the Company's stock price, a risk free interest rate of 0.28% and an expected volatility of 115%. The embedded derivatives were recorded on the condensed consolidated balance sheet as a compound derivative liability at an estimated fair value of \$1.4 million at issuance and created an offsetting debt discount that will be amortized over the life of the Note using the effective interest rate method.

The offset to debt arising from the recording of the compound derivative liability, the warrants and the associated issuance costs exceeded the debt proceeds by approximately \$60,000. This amount was recorded as a loss in Other Expense in the condensed consolidated statement of comprehensive loss for the quarter ended September 30, 2015.

The fair value of the compound derivative is 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. The fair value of the compound derivative increased \$1.3 million since issuance to \$2.8 million as of September 30, 2015. This change was recognized as a loss in Other Expense in the condensed consolidated statement of comprehensive loss for the quarter ended September 30, 2015.

The Company also evaluated the provision in the Note that increases the annual interest rate in the event of default and concluded that the initial value of this contingent feature is immaterial to the condensed consolidated financial statements as of September 30, 2015. The Company will evaluate the value of this contingent feature at each reporting period.

## 7. Fair Value Measurements

ASC Topic 820, *Fair Value Measurement*, defines fair value as the price that would be received to sell an asset or be paid to transfer a liability in an orderly transaction between market participants at the measurement date. The Company applies the following fair value hierarchy, which prioritizes the inputs used to measure fair value into three levels and bases the categorization within the hierarchy upon the lowest level of input that is available and significant to the fair value measurement. Level 1 inputs are quoted prices in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date. Level 2 utilizes quoted market prices in markets that are not active, broker or dealer quotations, or alternative pricing sources with reasonable levels of price transparency. Level 3 inputs are unobservable inputs for the asset or liability in which there is little, if any, market activity for the asset or liability at the measurement date.

The 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, 2015.

Balance as of January 1, 2015	\$	–
Issuances of compound derivative instrument		(1,419,105)
Change in fair value of compound derivative instrument		(1,344,542)
Balance as of September 30, 2015	\$	<u>(2,763,647)</u>

There were no financial instruments classified as Level 3 in the fair value hierarchy during the nine months ended September 30, 2014.

## 8. Stockholders' Equity

### *Common Stock*

On September 30, 2015, the Company filed an Amendment to the Articles of Incorporation with the Secretary of State of the State of Nevada to increase the authorized shares of common stock of the Company and change the par value per share of common stock (the "Amendment"). The Amendment authorizes the Company to issue 1,500,000,000 shares of Common Stock and changes the par value to \$0.001 per share. Prior periods have been reclassified to reflect the change in the par value per share to conform to the presentation in the present period.

### *Warrants*

In connection with the Company's issuance of the Note on July 1, 2015, the Company issued a warrant to purchase 10 million shares of common stock in accordance with the terms of the SPA (the "Warrant"). The Warrant has a five-year term and is exercisable commencing January 1, 2016. The exercise price per share under the Warrant is the lesser of \$0.20 or 120% of the Public Offering price, in the event there is a Public Offering. If the 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 10 million shares of common stock under the same terms as the Warrant (the "Contingent Warrant", or together referred to as the "Warrants"). The Company determined there is a high probability that the Note will not be repaid or converted within the period six months from the date of issuance, resulting in the issuance of the Contingent Warrant. As such, the Company concluded the Contingent Warrant is considered to be issued and outstanding as of the Note issuance date in accordance with ASC 815. The fair values of the Warrants were calculated using the Black-Scholes option pricing model. The key valuation assumptions used consist of the Company's stock price, a risk free rate of 1.70% and an expected volatility of 125%. Using an allocation of the Note proceeds between the relative fair values of the Warrants and the Note, the Company recorded the Warrants at a value of \$1.6 million on the condensed consolidated balance sheet as equity paid-in-capital. This created a debt discount of \$1.6 that will amortize from the date of issuance through the term of the Note.

In August 2015, the Company issued a warrant to purchase one million shares of common stock to a consultant upon engagement of services. The warrant has a term of five years and an exercise price of \$0.77. The warrant is a standalone instrument that is not puttable or mandatorily redeemable by the holder and is classified as an equity award. The Company determined that the fair value of the warrant is more reliably measureable than the fair value of the services received. As a result, the warrant was fair valued at \$272,000 at the time of issuance using the Black-Scholes option pricing model and will be expensed over the expected service period.

In connection with the Company's collaboration agreements, the Company issued warrants to purchase 10,425,000 shares of common stock to its collaborative partners on December 31, 2014. Also on December 31, 2014, a warrant to purchase 1,600,000 shares of common stock was issued to a non-employee director for consulting services provided to the Company. These warrants were fair valued at 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. Total expense associated with these collaboration agreement warrants recognized during the three and nine months ended September 30, 2015 were approximately \$243,000 and \$336,000 respectively. There were no warrants to purchase common stock issued during the nine months ended September 30, 2014.

## 9. Share-Based Compensation

Total share-based compensation related to stock options, common stock awards, warrants and Joint Share Ownership Plan awards was \$2.1 million and \$0.2 million for the three months ended September 30, 2015 and 2014, respectively, and \$2.3 million and \$0.7 million for the nine months ended September 30, 2015 and 2014, 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,	
	2015	2014	2015	2014
Research and development expenses	\$ 282,532	\$ 155,893	\$ 433,413	\$ 189,986
Administrative expenses	1,774,987	90,365	1,861,304	488,522
	<u>\$ 2,057,519</u>	<u>\$ 246,258</u>	<u>\$ 2,294,717</u>	<u>\$ 678,508</u>

### *Stock Option Modification*

During the three months ended September 30, 2015, the Company modified several employee stock option awards. The modification extends the expiry dates of 688,408 stock options through March 31, 2016. The Company accounted for the option modification under ASC Topic 718, *Compensation – Stock Compensation*, and as a result, recognized \$25,008 in incremental compensation expense during the three months ended September 30, 2015.

### *Employee Stock Options*

During the three and nine months ended September 30, 2015 and 2014, 16.3 million and 100,000 total stock options to purchase shares of common stock were granted under the Xenetic Biosciences, Inc. Equity Incentive Plan (the "Stock Plan"), respectively. The options granted during the three and nine months ended September 30, 2015 and 2014 have a weighted average grant date fair value per option share of \$0.28 and \$0.56, respectively. There were no employee stock option exercises during the nine months ended September 30, 2015. During the nine months ended September 30, 2014, a named executive of the Company exercised 1,984,080 stock options. Cash received from stock option exercise was \$101,933. The Company recognized compensation expense related to employee stock options of \$1,412,992 and \$92,108 during the three months ended September 30, 2015 and 2014, respectively, and \$1,497,295 and \$117,007 during the nine months ended September 30, 2015 and 2014, respectively.

### *Non-Employee Stock Options*

During the three and nine months ended September 30, 2015 and 2014, 1.0 million and zero total stock options to purchase shares of common stock were granted under the Stock Plan to non-employees, respectively. The options granted during the three and nine months ended September 30, 2015 have a grant date fair value of \$0.40. No non-employee stock options were exercised during the nine months ended September 30, 2015 or 2014. The Company recognized compensation expense related to non-employee stock options of \$177,351 and \$128,650 during the three months ended September 30, 2015 and 2014, respectively, and \$186,544 and \$140,096 during the nine months ended September 30, 2015 and 2014, respectively.

### ***Common stock awards***

The Company granted 371,292 and 37,218 common stock awards to non-employees during the three months ended September 30, 2015 and 2014, respectively, and 605,580 and 104,637 common stock awards to non-employees during the nine months ended September 30, 2015 and 2014, respectively. The Company measures the fair value of these awards using the fair value of the services provided, if available, as it is a more reliable measure of the fair value of the awards. If the Company is unable to determine the fair value of the services provided, the Company calculates the fair value of the awards based on the average stock price during the period in which performance of services is complete. The Company recognized compensation expense related to common stock awards of \$116,045 and \$25,500 during the three month periods ended September 30, 2015 and 2014, respectively, and \$167,045 and \$76,500 during the nine month periods ended September 30, 2015 and 2014, respectively. During the three and nine months ended September 30, 2015 and 2014, 527,535 and zero common stock award shares were issued, respectively. As of September 30, 2015 and 2014, 725,567 and 564,753 common stock awards were authorized but not issued, respectively.

### **10. Income Taxes**

During the three and nine months ended September 30, 2015 and 2014, there was no provision for income taxes as the Company incurred losses during these 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 \$17.2 million and \$13.8 million as of September 30, 2015 and December 31, 2014, respectively.

During 2014, the Company recorded an unrecognized tax position due to a claim for research and development tax credits. A full valuation allowance had been provided against the Company's research and development credits. In 2014, the Company determined that it was unable to obtain and compile the necessary information to support and defend the recoverability of the research and development tax credits, resulting in the write-off of the previously fully reserved balance and associated deferred tax asset. As of September 30, 2015 and December 31, 2014, the Company did not record any unrecognized tax positions.

### **11. 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 \$98,203 as prepaid rent as of September 30, 2015, of which \$68,742 is 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 \$60,768 is outstanding as of September 30, 2015, with \$43,270 recorded as a non-current liability. This liability is repayable as additional rent expense over the term of the lease and bears interest at 6%. In addition, the Company leases office space in London, U.K., which is due to expire in March 2017. The Company also leased office space in London, U.K. during 2014, however the lease was terminated in March 2015 in accordance with the terms of the lease.

### **12. Related Party Transactions**

In June 2015, the Company issued a promissory note for \$100,000 to Pharmsynthez with a maturity date of July 31, 2015 and a stated interest rate of 8.00% per annum. In July 2015, the Company repaid the promissory note and accrued interest in accordance with the terms of the promissory note.

In May 2011, the Company received a short term unsecured loan facility of up to \$1.7 million from SynBio, a related party, of which \$395,000 is outstanding as of September 30, 2015 and December 31, 2014, respectively (the "SynBio Loan"). The SynBio Loan had an interest rate of 8.04% per annum as of the date of grant, with interest payable upon repayment, which was to be seven months after the closing date of the loan. During 2012, the SynBio Loan matured and it was agreed by both parties that the loan could be called due with full repayment of the outstanding principal including accrued interest upon future agreement by both parties. It was also agreed that as of July 1, 2012, no further interest on the outstanding loan balance would be accrued. The SynBio Loan is recorded in current liabilities as of September 30, 2015. The SynBio Loan does not bear interest at the prevailing market rate for instruments with similar characteristics. In July 2015, the Company entered into a written deferral arrangement whereby SynBio agreed to defer all collections efforts or any default on the SynBio Loan until the earlier of January 31, 2016 or the Company's completion of a \$7 million financing.

The Company has various research, development, license and supply agreements with Baxalta, Serum Institute, SynBio and Pharmsynthez. Baxalta is a related party of the Company, with a share ownership in the Company of approximately 8.7% and 8.9% as of September 30, 2015 and 2014, respectively. Serum Institute is a related party of the Company, with a share ownership in the Company of approximately 9.2% and 9.4% as of September 30, 2015 and 2014, respectively. SynBio is an affiliate of the Company, with a share ownership in the Company of approximately 41.4% and 40.3% as of September 30, 2015 and 2014, respectively. Pharmsynthez is a related party of SynBio. In addition, two of the Company's directors are also in leadership positions at SynBio and Pharmsynthez.

### 13. Subsequent Events

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

In November 2015, the Company entered into an Asset Purchase Agreement (the "APA") with AS Kevelt, an Estonian company ("Kevelt"), and Pharmsynthez, parent of Kevelt (together referred to as the "Sellers"). Pursuant to the APA, Kevelt will transfer to the Company certain intellectual property rights with respect to the immunomodulatory product Virexxa™ held by Kevelt and the Sellers will grant the Company the worldwide right to develop, market and license Virexxa™ for all uses except for certain excluded uses in Russia, the Commonwealth of Independent States and certain other countries. In consideration, the Company will issue Pharmsynthez 100.5 million shares of its common stock. The APA also provides for the Company's issuance of 10% Senior Secured Convertible Promissory Notes of up to \$3.5 million to Pharmsynthez (the "New Notes") and warrants to purchase a number of shares of the Company's stock equal to 50% of the number of shares issuable under the New Notes. In the event that a New Note remains outstanding at April 30, 2016, Pharmsynthez shall be granted an additional warrant to purchase an additional number of shares of the Company's common stock equal to 50% of the number of shares issuable under the New Note. There is also a provision in the APA for the contingent sale of up to \$6.5 million of the Company's common stock in the event of a public offering of at least \$15 million. Also as part of the APA, Dmitry Genkin and Kirill Surkhov, shareholders and founders of Pharmsynthez, will assign a U.S. provisional patent application to the Company in exchange for 11 million shares of the Company's common stock.

In connection with the APA, certain terms in the Note and Warrants issued in July 2015 were modified to adjust the maturity and exercisable dates of the Note and Warrants, respectively.

The APA transaction is expected to be completed during the fourth quarter of 2015 and it is contingent upon the parties meeting their respective closing conditions as set forth in the APA.

## 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”, “might”, “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 successfully close the transactions contemplated in the Asset Purchase Agreement (the “APA”) entered into on November 13, 2015
- 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;
- any safety issues that arise with respect to our drug candidates;
- our ability to clinically demonstrate the safety or efficacy of our drug candidates;
- 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 Part I, Item 1A – Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2014.

## 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 as a single operating segment, is a clinical stage biopharmaceutical company that is focused on the research and development of certain pharmaceutical products for use in humans that incorporate the use of its patented and proprietary platform technologies that we believe will enable the creation of novel and next generation drug therapies primarily for orphan indications.

We hold over 147 U.S. and international patents issued, more than 90 patents pending and other proprietary rights to three distinct platform technologies that are designed to treat a variety of indications with potential use advantages over competing products.

### Significant Transactions and Recent Developments

#### *Financing*

On November 13, 2015, the Company has entered into an Asset Purchase Agreement (the “APA”) with AS Kevelt, an Estonian biotech company (“Kevelt”) and OJSC Pharmsynthez (“Pharmsynthez”, and together with Kevelt, “Sellers”). Pursuant to the APA, the Sellers will transfer to the Company certain intellectual property rights with respect to Virexxa™, and the Company will receive the worldwide rights to develop, market and license Virexxa for all uses, except for certain excluded uses within the Commonwealth of Independent States (the “CIS”), in exchange for 111.5 million shares of Company common stock and certain other consideration. Virexxa is a Phase II oncology drug candidate which is under investigation for the treatment of certain endometrial cancers. As part of this total consideration, the Company will also acquire Kevelt’s U.S. Orphan Drug designation for the use of Virexxa in the treatment of progesterone receptor negative endometrial cancer in conjunction with progesterone therapy.

The APA also contains a financing component wherein the Company will receive from Pharmsynthez up to \$3.5 million in bridge financing and a commitment of an additional \$6.5 million in financing as part of a planned capital raise of at least \$15 million and up-list to a national securities exchange.

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 “Note”). The SPA also provides for the issuance of certain warrants up to the amount of the Note. In July 2015, the Company issued the Note for \$3 million plus a warrant to purchase 10 million shares of common stock (the “Warrant”) in accordance with the terms of the SPA. The Note carries a term of one year and is convertible, in whole or in part, at the option of Pharmsynthez into shares of common stock at a conversion price of \$0.15. In the event that the Note remains outstanding at April 30, 2016, Pharmsynthez shall be granted an additional warrant to purchase an additional number of shares of the Company’s common stock equal to 50% of the number of shares issuable under the Note. The Warrant has a five-year term and is exercisable commencing January 1, 2016.

The SPA was amended in November concurrent with the execution of the APA in order to provide for the New Notes and the New Warrant.

This is not intended to be a full description of the APA. Please refer to the SEC Form 8-K filed on November 16, 2015 for a more complete description of this transaction.

## Technology Overview

The Company is currently in various stages of development with respect to its three core patented and proprietary technologies, those being PolyXen™ (for biologics), OncoHist™ (as a broad spectrum oncology therapy), and ImuXen™ (for vaccines).

The Company's three core technologies are summarized as follows:

PolyXen™	An enabling technology that utilizes Polysialic Acid ("PSA"), a biopolymer, consisting of a chain of sialic acids, which is a natural constituent of the human body. PSA is designed to extend the half-life in circulation in the human body for a variety of existing drug molecules and, thereby, to create potentially superior next generation drug candidates.
OncoHist™	A novel therapeutic platform that utilizes the properties of the human histone H1.3 ("H1.3") for the development of drug candidates for the treatment of 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 create new vaccines and improve the use and efficacy of certain existing vaccines for use in the human body. The technology is based on the co-entrapment of the nominated antigen(s) in a liposomal vesicle, a design that is intended to maximize both cell and immune system mediated responses.

All of the Company's current drug candidates are in the development stage and none has yet received regulatory approval for marketing in the U.S. by the U.S. Food and Drug Administration (the "FDA") or by any other applicable agencies in other countries.

## Our Business Strategy

The Company intends to advance the clinical development of its drug candidates through a combination of conducting its own in-house research and through the use of the outside services of contract manufacturing and research organizations. The OncoHist™ drug candidate for AML has been granted orphan drug designation by the FDA and European Medicines Agency ("EMA"). The Company expects to seek further orphan drug designations relating to this novel potential cancer therapeutic over the next twelve months, working in concert with the Dana Farber Cancer Institute. The advancement of OncoHist™ and the Company's other product candidates is dependent, in part, on several important co-development collaborations and strategic arrangements. Together with its collaborative partners, Baxalta, a shareholder in the Company, SynBio LLC ("SynBio"), a Russian pharmaceutical company and significant shareholder in the Company, OJSC ("Open Joint Stock Company") Pharmsynthez ("Pharmsynthez"), a Russian pharmaceutical company and related party to SynBio and Serum Institute of India Limited ("Serum Institute"), one of India's largest biotech companies and a shareholder in the Company, the Company is focused on developing its pipeline of next generation bio-therapeutics and novel orphan drugs in oncology based on the Company's PolyXen™, OncoHist™ and ImuXen™ technology platforms.

As part of the Company's strategy, it out-licenses the rights to drug candidates for research, development and commercialization within certain defined territories including twelve drug candidates in the Russian Federation and Commonwealth of Independent States ("CIS"), with respect to SynBio and Pharmsynthez, and one drug candidate in India, with respect to Serum Institute. SynBio, Pharmsynthez and Serum Institute are responsible for funding the research, development and commercialization of each drug candidate in those territories at their own expense. The out-license agreements contain provisions that allow the Company access to all underlying research materials and to receive royalties related to any of these drug candidates that may be approved and marketed in those territories. The Company utilizes its access to that data to determine which of those twelve drug candidates it believes are worthwhile to pursue for research, development and commercialization in the U.S. and elsewhere.

The Company's strategy is to develop its orphan drug candidates through to regulatory approval. The Company then plans to commercialize those orphan drug candidates. Non-orphan drug candidates vested in its pipeline via its collaborations include ErepoXen™; polysialylated oxyntomodulin, for diabetes and obesity; and a Multiple Sclerosis vaccine candidate, MyeloXen™. The Company intends to develop these candidates to a stage that will enable it to seek profitable out-licensing arrangements with major pharmaceutical companies for further development and eventual commercialization, in exchange for milestone payments and royalties from product sales. Its collaborative out-licensing agreements relating to the platforms are an integral part of its early-stage strategy.

Even with regard to its strategy of current and planned future co-development collaborations and out-licensing, the Company must raise additional capital in order to develop its drug candidates to the point of commercialization. The Company's management will regularly make evaluations in concert with the Company's Board of Directors as to when to seek additional capital through various financing structures for the purpose of pursuing its business strategy. Although the Company is optimistic, there can be no assurance that it will be successful in raising additional working capital in the future. If not successful, the Company's business could be adversely affected.



## Our Technologies

### *PolyXen*<sup>™</sup>

PolyXen<sup>™</sup> is a platform technology based on the concept of polysialylation. PSA is a polymer chain composed of sialic acids linked together. Sialic acid is found on the external membrane of a number of cell types in the body. In addition, it is a natural component expressed on the external membrane on a number of bacterial types. The chain of sialic acid molecules can be anywhere from four to over 200 individual sialic acid molecules in length. The Company uses the linear form of PSA called colominic acid. It is a natural, hydrophilic polymer isolated from a bacterial strain of *E. coli* K1. This natural glycan is negatively charged, non-toxic and is biodegradable. The PSA chain is extensively purified from large-scale bacterial cultures under Current Good Manufacturing Practices conditions, modified to specified sizes and then attached to defined sites on the therapeutic. Both the site of attachment and the length of the PSA chain can enhance the properties of the therapeutic.

The major effect of PSA addition to a therapeutic is to change the apparent hydrodynamic radius of the molecule. This physical alteration then changes a number of the biological characteristics of the therapeutic. The most noticeable, and perhaps the most relevant, is an extension of the lifetime of the therapeutic in blood circulation. This is due to the increase in the size of the drug, which results in a decrease in the clearance rate of the molecule in the kidney by glomerular filtration. In addition, studies have shown changes in other biological characteristics such as protease sensitivity and temperature sensitivity. An added benefit is that the conjugated molecules are less viscous in solution than comparable other technologies, providing the potential for easier injections and fewer injection site reactions. Furthermore, we believe that adding PSA to an existing marketed drug may allow for patent extension, thereby potentially creating a patent-protected next generation candidate.

The current standard for certain biologic delivery agents is Polyethylene Glycol (“PEG”) which is attached similarly to therapeutics. The mode of action between PSA and PEG is similar, increasing the apparent size of the molecule and thereby increasing the circulating time of the drug in the blood. PEGylation is a proven technology that can offer advantages in terms of pharmacokinetics and pharmacodynamics for therapeutics over non-modified, first generation molecules. There are a number of PEG-modified molecules on the market, in clinical trials and under development. However, PEGylation is considered to have limitations, such as non-biodegradability and, at high doses, may thereby result in intra-cellular accumulation, potentially leading to vacuole formation in the cells. In contrast, because PSA is a chain of sialic acids, which are natural constituents of the human body, it is biodegradable into individual sialic acid units. In addition, PEG in many cases has been shown to be immunogenic when coupled to proteins and can activate the complement system. PEG has also demonstrated limitations on a few select molecules. PSA has to date been shown to be non-immunogenic. We believe PSA may provide the advantages of PEG without many of its disadvantages, offering a potential advance over PEG molecules.

### *OncoHist*<sup>™</sup>

OncoHist<sup>™</sup> is based on research covered under our patent portfolio related to novel functions of histones. Histone H1 has strong anti-proliferative properties against cancer cells of different histological origin. This has been demonstrated extensively for hematologic malignancies, such as leukemias, lymphomas, and myelomas, and for tumors from other tissues. Susceptibility of cells to the cytotoxic effect of histones is determined by the ability of histone H1 to selectively destabilize the tumor cell membrane, which results in cell death.

A novel form of the molecule was developed by the Company and a patent filed for the protection of the new chemical entity, N-bis-met-histone 1.3 (OncoHist<sup>™</sup>) in use against cancer, providing patent protection at least until 2027. The activity of the new molecule was tested on 58 tumor cell lines derived from various tissues. Hematopoietic tumor cell lines were found to be among the most sensitive cell lines. The mechanism of action appears to be novel, involving the binding of OncoHist<sup>™</sup> to the cell membrane, which is completely different from that of other therapeutic agents on the market for hematopoietic cancers. Confirmatory work on this mode of action with more detailed analyses is being completed by Dana-Farber Cancer Institute (“Dana-Farber”). Hematopoietic tumor lines resistant to current chemotherapeutic agents have shown sensitivity to OncoHist<sup>™</sup>.

OncoHist's<sup>™</sup> potency and potential to inhibit growth of cells from various histological origins were confirmed through in-vitro testing against the U.S. National Cancer Institute 60 (“NCI-60”). OncoHist<sup>™</sup> was awarded orphan drug designation (Orphan Medicinal Product Designation (“OMPD”)) for treatment of AML by the European Commission in December 2007 and by the FDA in October 2008. OncoHist<sup>™</sup> was awarded an additional OMPD status for Acute Lymphocytic Leukemia (“ALL”) by the EMA.

A Phase I-II trial to evaluate the safety and tolerability of OncoHist<sup>™</sup> was conducted in 2008 at Saarland University, in Germany with 22 AML patients. Tolerability and safety results were favorable with indications of the drug being immunologically safe. Clinical effects were noted in seven patients with three partial remissions. Most notably, two patients who had received two treatment cycles each experienced stabilization of their disease for seven and 17 months.

A clinical safety trial with a planned 120 AML patients was in progress and being performed by SynBio in clinical centers in the Russian Federation. The aim of this trial was to examine the potential benefits of OncoHist™ in combination with standard HAM chemotherapy: high dose cytarabine with mitoxantrone. During execution of the SynBio AML trial, the Russian Ministry of Health issued changes in their standard of care for treating AML patients. High dose cytarabine chemotherapy was determined to offer no benefits in terms of efficacy as compared to lower dose therapy and was discontinued. The study was stopped and the study report is now in progress.

Based upon our analysis of data from the preliminary AML trial performed by SynBio in the Russian Federation, and data developed in Germany at Saarland University, the Company has undertaken pre-clinical development and IND-enabling animal studies in the U.S. in support of a planned phase I/II(a) IND filing with the FDA in the first half of 2017. Xenetic has had a pre-IND meeting with the FDA to discuss the OncoHist™ AML program. The FDA comments will be addressed by time of IND submission. A Phase I/II Non-Hodgkin's Lymphoma ("NHL") safety trial has been completed in Russia. As an integral part of the Company's strategy, we intend to await later stage clinical data on NHL to determine whether to progress this candidate into U.S. FDA trials.

## **Other Technologies**

### ***ImuXen™***

ImuXen™ is a patented platform technology based on the concept of simultaneous delivery of multiple Active Pharmaceutical Ingredients ("APIs") as antigens within the same liposome. The liposomes are composed of lipids that encapsulate an aqueous core. The APIs can be trapped in the core, be associated with the lipids, or both. Proteins, peptides, nucleic acids, polysaccharides and live or inactivated infectious agents can all be used as an API with the same liposome. Both the size and the lipid composition can be controlled which affects the biological properties of the liposome. Manufacturing involves the passive entrapment of the vaccine APIs by freeze drying commercially available liposomes with the antigens of interest.

Having multiple APIs formulated with the same liposome allows simultaneous delivery of the antigens to the same antigen-presenting cell. This may allow a more efficient immune response to all the agents presented. In addition, it is possible that multiple vaccines can be delivered with a single injection. Relevant pre-clinical studies have indicated a reduction in the dose required, a reduction in the number of doses required and a faster immune response time. This efficient immune response also may allow for use of antigens that traditionally give a poor antibody response.

This technology is not currently the focus of clinical development for the Company. However, through a license agreement with Pharmsynthez, there is a novel multiple sclerosis vaccine that is in clinical development in Russia.

A Phase I/II clinical trial to treat relapsing remitting multiple sclerosis and secondary progressive multiple sclerosis is in progress by SynBio in the Russian Federation. Peptides corresponding to antigenic sections of basic myelin protein were encapsulated within liposomes to be used as the therapeutic agent (MyeloXen™). Administration of MyeloXen™ to patients has occurred and follow-up monitoring is in progress. As an integral part of the Company's strategy, we await later stage clinical data on MyeloXen™ to determine whether to progress this candidate into FDA trials and eventual out-licensing.

## **Critical Accounting Estimates**

The preparation of our financial statements in conformity with U.S. generally accepted accounting principles 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, except as described below, since those critical accounting estimates described in our Annual Report on Form 10-K filed on April 15, 2015.

## Embedded Derivatives Related to Debt Instruments

The Note includes features that meet the criteria of embedded derivatives requiring bifurcation. The fair value of each embedded derivative is valued independently using a “with-and-without” method. The “with-and-without” methodology involves valuing the whole instrument on an as-is basis and then valuing the instrument without the individual embedded derivative. The difference between the entire instrument with all of the embedded derivatives compared to the instrument without the individual embedded derivative is the fair value of that individual derivative. The embedded derivatives are settled when the Note is settled. Therefore, there are three possible settlement mechanisms: the Note can be converted into equity, repaid early, or held to maturity.

We developed a set of potential outcomes resulting in the settlement of the Note consisting of a future public offering with conversion, default of the Note, the Note being converted to equity and the Note being held to maturity. These were included in a valuation model utilizing Monte Carlo Simulations to develop the fair value of the embedded derivatives, which included a simulation of the Company’s stock price with consideration provided for the expected volatility of the Company, the expected life of the host instrument, and risk free rate. The assumptions used in calculating the fair value represents our best estimates and involves inherent uncertainties and the application of our judgment. As a result, the use of alternate assumptions would result in outcomes that could be materially different. Additionally, the Company is required to update its assumptions and estimates at each valuation date. Based on updated circumstances, factors and knowledge of the Company at future valuation dates, then applicable assumptions and estimates could result in material changes in the estimated fair value of the embedded derivatives.

## RESULTS OF OPERATIONS

### *Comparison of Quarter Ended September 30, 2015 and 2014*

The comparison of our historical results of operations for the fiscal quarter ended September 30, 2015 to the fiscal quarter ended September 30, 2014 is set forth below:

<b>Description</b>	<b>Quarter Ended September 30, 2015</b>	<b>Quarter Ended September 30, 2014</b>	<b>Increase (Decrease)</b>	<b>Percentage Change</b>
Operating costs and expenses:				
Research and development	\$ (816,318)	\$ (1,905,234)	\$ (1,088,916)	57.2%
General and administrative	(2,984,484)	(1,203,126)	1,781,358	148.1%
Loss from operations	(3,800,802)	(3,108,360)	692,442	22.3%
Change in fair value of derivative	(1,344,542)	–	1,344,542	100.0%
Other expense	(50,526)	(72,877)	(22,351)	30.7%
Interest income	67	218	(151)	69.3%
Interest expense	(127,896)	(1,196)	126,700	10,593.6%
Total other income (expense)	(1,522,897)	(73,855)	1,449,042	1,962.0%
Net loss	<u>\$ (5,323,699)</u>	<u>\$ (3,182,215)</u>	<u>\$ 2,141,484</u>	<u>67.3%</u>

### Revenue

The Company recorded no revenues for the quarters ended September 30, 2015 and 2014.

### Cost of Revenue

The Company incurred no cost of revenue for the quarters ended September 30, 2015 and 2014.

### Research and Development

The Company engages in independent research and development (“R&D”) in connection with its various technologies. Overall, our corporate R&D expenses for the quarter ended September 30, 2015 decreased by approximately \$1.1 million, or 57% to \$0.8 million from \$1.9 million in the comparable quarter in 2014.

The table below sets forth the R&D costs incurred by the Company, by category of expense, for the quarters ended September 30, 2015 and 2014:

<b>Category of Expense</b>	<b>Quarter ended,</b>	
	<b>September 30, 2015</b>	<b>September 30, 2014</b>
Outside services and Contract Research Organizations	\$ 365,679	\$ 1,449,913
Share-based compensation expense	282,532	155,892
Salaries and payroll expenses	112,284	235,340
Rent	21,796	22,645
Lab consumables and other	34,027	41,444
Total research and development expense	<u>\$ 816,318</u>	<u>\$ 1,905,234</u>

***Research and Development by Category of Expense***

*Outside Services and Contract Research Organization Costs*

The decrease in outside services and contract research organization (“CRO”) costs of approximately 75% for the three months ended September 30, 2015 over the comparable period in 2014 is primarily due to the planned deferral of IND-enabling preclinical work conducted in connection with the OncoHist™ program due to working capital constraints. The costs of conducting the ongoing ErepoXen™ human clinical trials in Australia were relatively unchanged for the three months ended September 30, 2015 over the comparable period in 2014.

*Share-based Compensation*

Share-based compensation expenses increased approximately 81% for the three months ended September 30, 2015 over the comparable period in 2014. The change is primarily due to the normal fluctuations of existing awards plus expensing of stock option and warrant awards issued on December 31, 2014 and new stock option awards issued during the three months ended September 30, 2015, resulting in increased expenses during the current reporting period. There were no new awards affecting operations for the three months ended September 30, 2014.

*Salaries and Wages*

In aggregate, salaries and wages reflect a decrease of approximately 52% for the three months ended September 30, 2015 over the comparable period in 2014. This is related to the elimination of U.K.-based research personnel during 2014 as a result of the closing of the U.K. lab facility. There was no corresponding increase in U.S.-based research personnel during the three months ended September 30, 2015.

*Rent*

Rent expense allocated to research and development activities was relatively unchanged for the three months ended September 30, 2015 as compared to the three months ended September 30, 2014. During each period, the Company operated the same research and development facility, which shares its space with general and administrative employees.

*Lab Consumables and other*

The decrease in lab consumables and other expenses are due to normal fluctuations for lab supplies required for in-house research activities and the net aggregate change of all other miscellaneous R&D costs.

## General and Administrative

General and administrative expenses increased by approximately \$1.8 million, or 148%, for the quarter ended September 30, 2015 to \$3.0 million from \$1.2 million in comparable quarter in 2014. The most significant drivers of the change were related to increases of approximately \$1.7 million in stock compensation expense and \$0.1 million in legal and other professional consulting fees. The increase in stock compensation is primarily due to stock compensation expense recognized related to option awards granted to employees and consultants and common stock and warrant awards granted to consultants during the period. The stock compensation expense related to existing awards and new grants was much lower during the same period in 2014 due to the lower number of new grants as compared to the current period. The increase in legal and other professional consulting fees is associated with services provided in connection with the drafting of the SPA. There was not a similar financing that was in progress or completed during the same period in 2014.

## Change in Fair Value of Derivative

The loss of approximately \$1.3 million is recognized on the change in fair value of the Company's compound derivative instrument as of September 30, 2015. The Company did not have debt instruments with embedded derivatives outstanding during the comparable period in 2014.

## Other Expense

Other expense decreased \$22,351, or 31% to \$50,526 for the three months ended September 30, 2015 from expense of \$72,877 in the comparable quarter in 2014. The change is primarily due to a decrease in foreign currency exchange losses resulting from the change in functional currency of the Company's foreign entities to the reporting currency during the second quarter of 2015. This was offset by a charge recognized on the issuance of the Note and Warrant during the three months ended September 30, 2015 of approximately \$60,000.

## Interest Income

Interest income decreased by approximately \$151, or approximately 69%, to \$67 for the three months ended September 30, 2015 from \$218 during the three months ended September 30, 2014. The decrease is related to decreases in average cash balances maintained in interest bearing accounts.

## Interest Expense

Interest expense increased by \$126,700 for the three months ended September 30, 2015 to \$127,896 from \$1,196 during the three months ended September 30, 2014. The increase in interest expense is primarily due to interest charges associated with the Note. There was not a similar promissory note in the comparable period in 2014. The Company also recognized interest expense related to a financing arrangement with the landlord of the Company's office and laboratory lease in the U.S., which commenced in January 2014.

## Comparison of Nine Months Ended September 30, 2015 and 2014

The comparison of our historical results of operations for the nine months ended September 30, 2015 to the nine months ended September 30, 2014 is set forth below:

Description	Nine Months Ended September 30, 2015	Nine Months Ended September 30, 2014	Increase (Decrease)	Percentage Change
Operating costs and expenses:				
Research and development	\$ (2,407,141)	\$ (3,502,805)	\$ (1,095,664)	31.3%
General and administrative	(4,723,109)	(5,204,541)	(481,432)	9.3%
Loss from operations	(7,130,250)	(8,707,346)	(1,577,096)	18.1%
Change in fair value of derivative	(1,344,542)	–	1,344,542	100.0%
Loss on disposal of subsidiaries	–	(1,069,675)	(1,069,675)	100.0%
Other income (expense)	(276,041)	(235,484)	40,557	17.2%
Interest income	1,155	11,960	(10,805)	90.3%
Interest expense	(130,408)	(3,569)	126,839	3,553.9%
Total other expense	(1,749,836)	(1,296,768)	453,068	34.9%
Net loss	\$ (8,880,086)	\$ (10,004,114)	\$ (1,124,028)	11.2%

## Revenue

The Company recorded no revenues for the nine months ended September 30, 2015 and 2014.

## Cost of Revenue

The Company incurred no cost of revenue for the nine months ended September 30, 2015 and 2014.

## Research and Development

The Company engages in independent research and development (“R&D”) in connection with its various technologies. Overall, our corporate R&D expenses for the nine months ended September 30, 2015 decreased by approximately \$1.1 million to \$2.4 million from \$3.5 million in the comparable period in 2014.

The table below sets forth the R&D costs incurred by the Company, by category of expense, for the nine months ended September 30, 2015 and 2014:

Category of Expense	Nine Months Ended,	
	September 30, 2015	September 30, 2014
Outside services and Contract Research Organizations	\$ 1,395,814	\$ 2,452,259
Share-based compensation expense	433,414	186,886
Salaries and payroll expenses	379,766	596,410
Rent	66,709	54,851
Lab consumables	23,406	19,966
Other	108,032	192,433
Total research and development expense	<u>\$ 2,407,141</u>	<u>\$ 3,502,805</u>

### *Research and Development by Category of Expense*

#### *Outside Services and Contract Research Organization Costs*

The decrease in outside services and CRO costs of approximately 43% for the nine months ended September 30, 2015 over the comparable period in 2014 is primarily due to planned deferral of IND-enabling preclinical work conducted in connection with the OncoHist™ program due to working capital constraints. The costs of conducting the ongoing ErepoXen™ human clinical trials in Australia were relatively unchanged for the nine months ended September 30, 2015 over the comparable period in 2014.

#### *Share-based Compensation*

Share-based compensation expenses increased approximately 132% for the nine months ended September 30, 2015 over the comparable period in 2014. The change is primarily due to the normal fluctuations of existing awards plus expensing of stock option and warrant awards issued on December 31, 2014 and new stock option awards issued during the three months ended September 30, 2015, resulting in increased expenses during the current reporting period. There were no new awards affecting operations for the nine months ended September 30, 2014.

#### *Salaries and Payroll Expenses*

In aggregate, salaries and payroll expenses reflect a decrease of approximately 36% for the nine months ended September 30, 2015 over the comparable period in 2014. This is related to the elimination of U.K.-based research personnel during 2014 as a result of the closing of the U.K. lab facility. There was no corresponding increase in U.S.-based research personnel.

#### *Rent*

Rent expense allocated to research and development increased approximately 22% for the nine months ended September 30, 2015 over the comparable period in 2014. During each period, the Company operated the same research and development facility, which shares its space with general and administrative employees. While the overall rent expense for this facility did not change during these periods, the expense allocated to research and development increased during the nine months ended September 30, 2015 due to a change in the Company's method of allocation.

### *Lab Consumables*

The increase in lab consumables expense is due to normal fluctuations for lab supplies required for in-house research activities.

### *Other*

The decrease in other expense results from the net aggregate change of all other miscellaneous R&D costs.

## **General and Administrative**

General and administrative expenses decreased by approximately \$0.5 million, or 9% for the nine months ended September 30, 2015 to \$4.7 million from \$5.2 million in the comparable period in 2014. The most significant drivers of the change were related to a decrease of approximately \$0.8 million in legal and other professional consulting fees, \$0.7 million in accounting and regulatory fees and \$0.2 million in travel expenses. This was net by an increase of \$1.4 million in stock compensation expense. The current period decreases in legal and other professional consulting fees, accounting and regulatory fees and travel expenses are associated with the Company's strategic transition from a U.K.-based, London AIM quoted, organization, to a U.S.-based, publicly traded company, which was initiated during 2013 and substantially completed in the first half of 2014. While there were no costs associated with this strategic transition during the comparable period in 2015, the overall period over period decrease in legal and other professional consulting fees was net by costs incurred in connection with the drafting of the SPA during the nine months ended September 30, 2015. Stock compensation expense increased primarily due to the expense recognized on option awards granted to employees and consultants and common stock and warrant awards granted to consultants during the nine months ended September 30, 2015. This increase was net by approximately \$0.3 million in charges related to the accelerated vesting of Joint Share Ownership Plan ("JSOP") awards during the nine months ended September 30, 2014. There were no charges associated with JSOP awards during the comparable period in 2015.

## **Loss on Disposal of Subsidiaries**

The loss on disposal of subsidiaries for \$1,069,675 for the nine months ended September 30, 2014 arose in connection with the Hive Out Agreement. Pursuant to the Hive Out Agreement the Company received ten million outstanding shares of its common stock in exchange for 100% of the outstanding common stock of the subsidiaries and cash in the amount of \$430,000. The nine months ended September 30, 2015 had no comparable transaction. The Company does not currently intend to dispose of any other subsidiaries in the near future. Please refer to the Company's Annual Report filed on Form 10-K filed on April 15, 2015 for further information pertaining to the loss on disposal of subsidiaries.

## **Change in Fair Value of Derivative**

The loss of approximately \$1.3 million is recognized on the change in fair value of the Company's compound derivative instrument as of September 30, 2015. The Company did not have debt instruments with embedded derivatives outstanding during the comparable period in 2014.

## **Other Expense**

Other expense increased \$40,557, or 17% to \$276,041 for the nine months ended September 30, 2015 from \$235,484 in the comparable period in 2014. The increase is primarily due to a charge recognized on the issuance of the Note and Warrant during the period of approximately \$60,000.

## **Interest Income**

Interest income decreased by \$10,805, or approximately 90%, to \$1,155 for the nine months ended September 30, 2015 from \$11,960 during the nine months ended September 30, 2014. The decrease is related to decreases in average cash balances maintained in interest bearing accounts.

## **Interest Expense**

Interest expense increased by \$126,839 for the nine months ended September 30, 2015 to \$130,408 from \$3,569 during the nine months ended September 30, 2014. The increase in interest expense is primarily due to interest charges associated with the Note. There was not a similar promissory note in the comparable period in 2014. The Company also recognized interest expense related to a financing arrangement with the landlord of the Company's office and laboratory lease in the U.S., which commenced in January 2014.

## Liquidity and Capital Resources

We have historically relied upon equity financing to fund our operations. Since 2005, we have raised approximately \$47 million in equity financing, including \$10 million from the sale of shares to Baxter in January 2014, while recording revenues of approximately \$10 million during that same period. Approximately 90% of that revenue is from a single customer, Baxter, in connection with milestone receipts and fees for services. We expect the majority of our funding through equity or equity linked instruments to continue as a trend for the foreseeable future.

For the nine months ended September 30, 2015, our working capital decreased due to our net loss of approximately \$8.9 million and cash used in operating activities of \$4.2 million, which 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.

At September 30, 2015 and December 31, 2014, we had a working capital deficit of \$4.6 million and working capital of \$0.1 million, respectively. As of September 30, 2015, we had \$1.2 million in cash and \$6.1 million in total current liabilities. As of December 31, 2014, we had cash and current liabilities of \$2.5 million and \$2.7 million, respectively. Included in the working capital deficit at September 30, 2015 is the compound derivative liability of approximately \$2.8 million, a trade payable in the amount of approximately \$485,000 that is being disputed by the Company and a loan from a related party, SynBio, in the amount of \$395,000 (the "SynBio Loan") that is subject to alternative payment arrangements. In July 2015, the Company entered into a written deferral arrangement in connection with the SynBio Loan whereby SynBio agreed to defer all collections efforts or any default on the note until the earlier of January 31, 2016 or the Company's completion of a \$7 million financing.

On July 1, 2015, the Company entered into the SPA with Pharmsynthez for the issuance of the Note, which provided net proceeds of approximately \$3 million for the general working capital needs of the Company.

The Company will be required to raise additional working capital in order to meet its financial obligations for the next 12 months. In November, we concluded negotiations with existing investors in connection with raising bridge financing that will allow us to continue our operations while we pursue a larger capital raise. Concurrent with entering into the APA, on November 13, 2015, we entered into a 1<sup>st</sup> amendment to the SPA (the "Amended SPA") wherein Pharmsynthez will purchase from the Company up to \$3.5 million of additional 10% Senior Secured Convertible Promissory Notes (the "New Notes"). The Amended SPA provides that Pharmsynthez will purchase the New Notes in tranches. The first tranche of \$1 million is to be received by the Company within five days following execution of the APA and, upon proper notice from the Company, the second tranche of \$500,000 in November 2015, the third tranche of \$1 million in December 2015 and the fourth tranche of \$1 million in February 2016.

Further, pursuant to provisions included in the APA, Pharmsynthez agrees to invest an additional \$6.5 million as part of our planned total capital raise of at least \$15 million (the "Additional Investment"). The Additional Investment is calculated by subtracting the actual amount of their purchases of New Notes from Pharmsynthez's total \$10 million financing commitment.

The total amount of financing contemplated in the APA is \$18.5 million consisting of \$3.5 million in the New Notes, \$6.5 million in the Additional Investment and a minimum of \$8.5 million in other public offering proceeds. The Company believes this total financing will be sufficient for the Company to meet its financial obligations and to continue its planned operations for the next 12 months. In the event that the Company is unsuccessful in raising the minimum of \$8.5 million in other public offering proceeds, the APA would result in only \$10 million in total financing. This outcome would require the Company to seek additional financing and/or defer certain research and development activities. Although the Company is optimistic that it will be successful in obtaining the financing contemplated in the APA, there can be no assurance that it will be able to do so.

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 Baxalta. 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 12 months; however, there can be no assurance that future receipts will ever become due because they are contingent on positive outcomes from Baxalta'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 do not expect any new income to be generated from such out-licensing before Q1 2016 at the earliest. 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.

Baxalta currently holds a share warrant entitling them to subscribe for approximately 4.59 million new shares of common stock in the Company at a price of \$0.4660 per share. These warrants are due to expire in June 2016. We do not expect Baxalta to exercise these warrants at the prevailing average price of the stock of the Company as quoted on the OTCQB, and in any event, not before June 2016.

Although we are optimistic about our ability to raise additional working capital, there can be no assurance that we will be successful, or even if the Company is successful, that it will be able to do so on commercially reasonable terms. Further, due to the uncertainties inherent in the clinical research process and unknown future market conditions, there can be no assurance that either the Company's ErepoXen™ candidate will lead to any future fees or that Baxalta itself will be successful in initiating human clinical trials in the estimated timeframe or that the underlying product will meet the clinical milestones necessary to trigger any payment to the Company under the terms of its license agreement with them. As a result, these conditions raise substantial doubt regarding our ability to continue as a going concern.

### **Cash Flows from Operating Activities**

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 used in operating activities for the nine months ended September 30, 2014 totaled approximately \$10.0 million, which includes a net loss of approximately \$10.0 million and \$0.4 million paid out in connection with the Hive Out Agreement. These were partially offset by \$1.7 million in non-cash charges for share-based compensation and loss on disposal of subsidiaries and reduced by approximately \$1.3 million in net increase in account receivable and reductions in accounts payable and accrued expenses. The \$10.0 million includes cash expenses of approximately \$1.8 million in salaries, employee fringe benefits and related taxes, including scientific staff, \$1.9 million in professional consultants, approximately \$1.2 million in program-specific clinical development costs, \$0.9 million in legal fees and \$0.9 million in accounting and tax consultants, \$0.6 million in regulatory and investor relations expenses and \$0.1 million in corporate insurances.

### **Cash Flows from Investing Activities**

For the nine months ended September 30, 2015 and 2014, respectively, there were no significant cash sources or uses from investing activities.

### **Cash Flows from Financing Activities**

During the nine months ended September 30, 2015, we raised \$3.0 million and \$0.1 million with the issuances of the Note and a short-term promissory note, respectively. From the proceeds of the Note, we repaid our \$0.1 million short-term promissory note.

During the nine months ended September 30, 2014, we raised \$10.0 million in financing activities from the sale of approximately 10.7 million shares of common stock to Baxter Healthcare SA. We also raised approximately \$0.1 million from proceeds in connection with the exercise of approximately 1.98 million stock options by our Chief Executive Officer in January 2014. These proceeds were net by a payment of approximately \$0.3 million on a related party loan.

## 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.

## Recent Accounting Pronouncements

In April 2015, Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2015-03, *Interest – Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs* (“ASU 2015-03”). ASU 2015-03 requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. This guidance is effective for annual reporting periods beginning after December 15, 2015, and interim periods within fiscal years beginning after December 15, 2016. The Company early adopted ASU 2015-03 in July 2015, as permitted. There is no impact of early adoption of ASU 2015-03 on the Company’s condensed consolidated financial statements.

In August 2014, the FASB issued ASU 2014-15, *Presentation of Financial Statements – Going Concern (Subtopic 205-40)* (“ASU 2014-15”). ASU 2014-15 defines management’s responsibility to evaluate whether there is substantial doubt about an organization’s ability to continue as a going concern and provides guidance on the related footnote disclosures. This guidance is effective for annual reporting periods beginning after December 15, 2016, and interim periods within annual periods beginning after December 15, 2016. Early application is permitted. The Company is currently evaluating the impact of this new standard.

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)* (“ASU 2014-09”). ASU 2014-09 supersedes the revenue recognition requirements in Accounting Standards Codification (“ASC”) Topic 605, *Revenue Recognition*, and most industry-specific guidance. The core principle of the guidance is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled to in exchange for those goods or services. This guidance is effective for annual reporting periods beginning after December 15, 2017, including interim periods within that reporting period, under either full or modified retrospective approach. Early application is permitted as of annual reporting periods beginning after December 15, 2016. The Company is currently evaluating the impact of this new standard on its revenue recognition policy.

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

## Available Information

Our website address is [www.xeneticbio.com](http://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](http://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 in Part 1, Item 1A – Risk Factors of our Annual Report on Form 10-K for the year ended December 31, 2014 (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**

In July 2015, the Company issued a \$3 million 10% Senior Secured Collateralized Convertible Promissory Note (the “Note”) plus a warrant to purchase 10 million shares of common stock to OJSC Pharmsythez. The net proceeds of approximately \$3 million were used for general working capital needs of the Company. This Note was sold in a private placement and was issued by the Company pursuant to an exemption from the registration either (a) under the Securities Act generally, in that the transactions are between an issuer and sophisticated investors and do not involve any public offering within the meaning of Section 4(a)(2) or (b) under Regulation S promulgated under the Securities Act in that offers, sales and issuances are not made to persons in the United States and no directed selling efforts are made in the United States.

In August 2015, the Company issued 527,535 shares of the Company’s common stock to non-employee consultants in exchange for services provided to the Company. The shares were not registered under the Securities Act, or the securities laws of any state, and were offered and sold in reliance on the exemption from registration afforded by Section 4(a)(2) and Regulation D (Rule 506) under the Securities Act and corresponding provisions of state securities laws, which exempt transactions by an issuer not involving any public offering.

### **ITEM 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.



## EXHIBIT INDEX

<b>EXHIBIT NUMBER</b>	<b>DESCRIPTION</b>
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 September 30, 2015, 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

**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 16, 2015

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

**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 16, 2015

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



**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, 2015, 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 16, 2015

By: /s/ Michael Scott Maguire

Michael Scott Maguire

Chief Executive Officer, President and Chief Financial Officer